



Queen Margaret University  
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A COGNITIVE BEHAVIOURAL THERAPY IN THE FORM OF  
SELF-HELP FOR PATIENTS WITH SLEEP DISTURBANCE AND  
CHRONIC HEALTH CONDITIONS

NICOLA KAZAMIA

A thesis submitted in partial fulfilment of the requirements for  
the degree of Professional Doctorate in Health Psychology

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## **DECLARATION**

I hereby certify that I am the sole author of the current thesis, which is the result of my own original doctorate research study. The current thesis has not been previously accepted by, or submitted, to any other University or Institution for any other degree. Where any information has been obtained from the published work of others, it has been acknowledged within the text and included in the references.

The current work was carried out under the guidance of my first supervisor, Dr. Vivienne Chisholm, and my second supervisor, Dr. Joanne Fox, at Queen Margaret University, Edinburgh.

Nicola Kazamia

## ABSTRACT

**Background:** Sleep disturbance, including insomnia disorder, is common among patients with chronic health conditions, and is associated with psychological difficulties and impaired health-related quality of life (HRQoL). Less is known about whether a similar relationship exists in individuals with chronic health conditions who do not have a clinical diagnosis of sleep disturbance (NCSD). Recent evidence suggests that Cognitive Behavioural Therapy (CBT) in the form of self-help (SH) is an effective treatment for individuals with chronic health conditions and has the advantage of low cost and ease of access. Any form of sleep disturbance may be perceived as problematic for individuals with chronic health conditions. This study aims to: a) examine whether the NCSD population with chronic health conditions at baseline have poor sleep quality, insomnia symptoms, high levels of psychological distress (anxiety, depression and stress), sleep-related dysfunctional beliefs and impaired HRQoL, and b) assess the effectiveness of the CBT-SH booklet.

**Method:** Participants were recruited from outpatient clinics and received a 6-week CBT-SH booklet for sleep-related problems. Outcome measures included evaluations of subjective sleep quality and the severity of insomnia symptoms, psychological distress (anxiety, depression and stress) sleep-related dysfunctional beliefs and HRQoL. Measures were completed before and after the intervention.

**Results:** Forty-nine participants (44 females) completed the study. Prior to the intervention, 46 participants reported poor sleep quality and 47 participants reported clinical or subthreshold insomnia. Mean scores for the measures of psychological distress indicated moderate levels of anxiety, depression and stress and sleep-related dysfunctional beliefs respectively. HRQoL was also impaired. Following the CBT intervention, participants showed significant improvements in sleep outcomes, sleep-related dysfunctional and stress levels. No significant differences were found in HRQoL depression and anxiety outcomes.

**Conclusion:** A brief CBT-SH booklet for sleep-related problems is effective for patients with chronic health conditions and NCSD in clinical settings.

*Key words:* sleep disturbance; sleep quality; chronic health conditions; cognitive behavioural therapy; self-help.

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# **1. Introduction**

This study concerns a Cognitive Behavioural Therapy (CBT) based intervention in the form of a self-help booklet for a clinical population with a self-reported sleep disturbance problems. In order to establish the context of the current study, the subsequent chapter begins by addressing and defining the most important key terms of the related literature of relevance to the current study in order to aid understanding of the theoretical framework and empirical research of the study.

Firstly, it provides an understanding of the nature of sleep disturbance, followed by an overview of insomnia, which is the most common sleep disorder that may coexist with or without medical or psychiatric disorder. Subsequently, the current review provides the background of a number of chronic health conditions and their documented link with sleep-related problems. Furthermore, it reviews the evidence for the factors contributing to and maintaining sleep problems in patients with chronic health conditions as well as the negative consequences of sleep-related problems on the individual's quality of life.

Secondly, it provides an overview of the vast treatments available in managing sleep problems such as pharmacological, complementary or alternative therapies (e.g. herbal remedies), behavioural and psychological therapies along with their scientific evidence for managing sleep problems. Emphasis on the management of sleep problems is given to the behavioural and psychological therapies and, in particular, to CBT for sleep-related problems.

## **2. LITERATURE REVIEW**

### **2.1. The nature of sleep disturbance research**

Initially sleep was considered a passive or dormant activity in our daily lives whereas, today, it is considered an active physiological process, since our brain is active during sleep (American Sleep Association, 2015). Sleep is considered as an essential need for a healthy life and overall well-being, (National Sleep Foundation (NSF), 2015), since it affects physical and mental health (American Sleep Association, 2015). Subsequently, good sleep is fundamental for a healthy life (Buysse, 2014).

Both quantity and quality are important for good sleep (NSF, 2015). Poor sleep quality is a clinical construct, since sleep quality disturbances are common and poor sleep quality may be the result of a sleep disorder or a medical disease (Buysse et al., 1989). Buysse et al. (1989, p.194) consider sleep quality to be a ‘complex phenomenon that is difficult to define and measure objectively’. The quality of sleep can be measured quantitatively – by measuring sleep duration, sleep latency or sleep arousal – or qualitatively by measuring the subjective ‘depth’ or ‘restfulness’ of sleep (Buysse et al., 1989).

#### **2.1.1. Sleep Disturbance Classified as Insomnia**

Insomnia is the most prevalent sleep disorder encountered among adults of any age (National Institute of Health (NIH), 2005) and the second most common health complaint after pain (Morin, 1993). Thus it has received considerable attention in the existing literature. Insomnia is defined as disturbed sleep under conditions, which are conducive to sleep. The disturbance may manifest itself in a number of ways, including one or more of the following: 1) difficulty in initiating (sleep-onset), 2) difficulty in maintaining sleep, or 3) waking prematurely. Nonrestorative or poor sleep can also be included in this definition (NIH, 2005).

In terms of its duration, insomnia may be classified as acute insomnia and chronic insomnia (e.g. 6 months or one month or more) (NIH, 2005). Also, insomnia can be characterised as primary insomnia (PI) when no existing disorder has been identified and secondary insomnia (SI), the result of a medical, psychiatric condition or a substance (McCrae & Lichstein, 2001a). Despite their causal differences, both primary and secondary insomnia share similar features in terms of their definition (McCrae & Lichstein, 2001a). The NIH (2005) suggested a terminology-related shift from 'secondary insomnia' to 'comorbid insomnia' because, on the one hand, the direction of causality between condition and insomnia is unclear and, on the other hand, the term 'secondary insomnia' may result in under-treatment. Therefore, it may be concluded that individuals with chronic health conditions and sleep problems warrant independent treatment for sleep-related problems.

Studies in the field of sleep have mainly used clinical diagnostic criteria for insomnia or for comorbid insomnia and/or other structured screened interviews or various insomnia severity measurements to diagnose or assess individuals with clinical sleep disorder (e.g. insomnia). In contrast, the current study used a pragmatic, real-world approach in terms of defining and confirming sleep-related problems among patients with chronic health conditions.

Since it is possible that any form of sleep disruption may, to some degree, have an effect on an individual with chronic health conditions, the current study relied on individuals' self-reporting sleep-related problems or sleep disturbance and, for the purposes of this thesis, insomnia and sleep disturbance are not differentiated since they are not clinically evaluated or diagnosed and therefore the term 'non-clinical sleep disturbance' (NCSD) is utilised (e.g. individuals who report sleep disturbances which are not clinically established like insomnia but which, nonetheless, may be perceived as problematic). In particular, this approach was preferred in order to keep the current study as close as possible to the real-world context, since sleep disturbance is a very broad term that may have different meanings for different people.

In general, sleep disturbance may refer to any real disruption in sleep patterns and a brief and effective treatment may prove to be beneficial to patients, despite the severity of the sleep problem.

Until recently, no studies had examined NCSD in patients with chronic health conditions and no studies had examined specifically the effectiveness of CBT-I in the form of a self-help (SH) booklet in a NCSD population with at least one chronic health condition who self-reported sleep-related problems. Therefore, based on this observation, the purpose of the current study is to assess the effectiveness of the CBT-I SH booklet for patients with chronic health conditions and with NCSD. However, before doing so, it is important to understand the aetiology of the different factors in affecting and maintaining insomnia.

### **2.1.2. The Aetiology of Insomnia**

There is no agreed understanding of the mechanisms contributing to the pathophysiology of insomnia (Edinger & Means, 2005). Spielman (1986; Spielman & Glovinsky, 1991) proposed a behavioural model known as the ‘3P-model of insomnia’, which was further expanded by Morin (1993).

This model describes three different factors that operate in the development and maintenance of insomnia: 1) predisposing conditions or long-term traits (e.g. arousability, family history or genetic traits, gender); 2) precipitating factors (myriad stressful life events, such as work, divorce, death and illness such as uncontrolled symptoms such as pain fatigue, etc.); and 3) perpetuating factors (e.g. maladaptive behaviours and cognitive misrepresentations) that maintain or exacerbate insomnia (Morin, 1993).

Morin (1993) in particular suggests that insomnia can be viewed as an interaction between arousal (e.g. emotional, cognitive, physiological), dysfunctional cognitions (e.g. worry, rumination, unrealistic expectations, misattributions/amplifications), maladaptive habits (e.g. excessive time in bed, napping, sleep-incompatible activities, irregular sleep schedule) and concerns about consequences (e.g. mood

disturbance, fatigue, social discomfort). The relationship among these different factors is bi-directional (Morin, 1993).

In sum, the 3-P model of insomnia suggests that various factors, to different degrees, may play a role in increasing the likelihood of an individual developing sleep disturbance. Precipitating factors, such as stressful events, may disturb sleep but the predominant factors that maintain chronic insomnia are perpetuating factors (e.g. cognitions and maladaptive sleep habits) (Morin, 1993). Consequently, the 3-P model provides the theoretical framework for understanding how patients with chronic health conditions may be engaged in the perpetuating factors that maintain sleep problems. However, very little is known about non-clinical sleep disturbance, its impact and suggested treatments to alleviate its outcomes, hence the current study, aims to address this gap in the literature.

### **2.1.3. Measuring sleep disturbance insomnia symptoms and treatment outcomes**

Any study requires reflection on measurement and in the field under consideration, there is a range of tools that are used to measure sleep disturbance, including both objective and subjective self-reporting measures (Buysse, Ancoli-Israel, Edinger, Lichstein & Morin 2006; Menefee et al., 2000).

#### **2.1.3.1. Objective methods**

Polysomnography (PSG) is an objective measurement, which is mainly used in the screening and assessment of sleep disturbance (Buysse et al., 2006). This particular type of objective measurement can be used at home or in the lab, and is considered the most sensitive method for distinguishing wakefulness from sleep (NIH, 2005). Though, PSG is not a cost-effective method (NIH, 2005; Menefee et al., 2000).

A different objective method is actigraphy, which can be used to provide an exact measure of global sleep parameters (e.g. total sleep/wake time and time in bed) (Morin, 2003). Evidence suggests that actigraphy is an acceptable and reliable method for measuring the duration of sleep (Petit, Azad, Byszewski, Sarazan, & Power, 2003).

#### **2.1.3.2. Subjective methods**

Subjective methods include various types of self-reporting measures that assess sleep disturbance (Pigeon, 2010a). The most commonly used measures, with established reliability and validity, are the Pittsburgh Sleep Quality Index (PSQI), which measures the overall sleep experience by distinguishing poor sleepers from good sleepers (Buysse et al., 1989) and the Insomnia Severity Index (ISI), which assesses insomnia severity (Bastein, Vallieres & Morin 2001) (Pigeon, 2010a).

Alternative subjective tools include sleep diaries or sleep logs (e.g. recording sleep habits such as time to bed, minutes to fall asleep, number and duration of awakenings etc. for at least two weeks prior to therapy, throughout and at end the of the treatment) (Pigeon, 2010a; Petit et al., 2003). Sleep diaries have less sensitivity to recall bias (Buysse et al., 2006) and are considered the most beneficial subjective tools in measuring sleep problems (Petit et al., 2003;Pigeon 2010a).

In general, the different methods of assessing sleep disturbances have their own strengths and limitations. Self-report questionnaires form the basis of assessment measures in insomnia research because they are the main tool used by clinicians for treating patients with insomnia, they are cost-effective (Moul, Hall, Pilkonis & Buysse, 2004) and can be easily administered (Morin, 2003; Menefee et al., 2000) and scored (Morin, 2003). In addition, as discussed, subjective self-reports are an important assessment tool, because insomnia is a subjective complaint, and an individual's perceptions of treatment efficacy are more valid than objective measurements (Martin, Shochat, & Ancoli-Israel, 2000).

On the other hand, in general, subjective methods require more resources and less cost-effective in assessing sleep of assessing sleep (Menefee et al., 2000).

In summary, validated and reliable methods for measuring sleep problems are essential, since insomnia is a subjective complaint and sleep quality can only be measured using self-reports. In addition, self-report measures are the easiest and most convenient method of assessing sleep-related problems and self-report measures also fit well within the real world context. Therefore, self-report questionnaires are used in the current study.

Insomnia and sleep-related problems in general are prevalent health problems among patients with various chronic health conditions and are associated with emotional distress and poor quality of life. The section below provides a further understanding of the relationship between chronic health conditions and sleep problems.

## **2.2. Chronic Health Conditions and Sleep Disturbance**

One of the most important reasons for investigating non-clinical sleep disturbance is the well-established link between chronic health conditions and sleep-related problems, in particular insomnia.

A chronic health condition or long-term condition (LTC) is defined by the UK Department of Health (2010) as a condition that cannot be cured, though it may be controlled by pharmacological treatments or other types of therapies. Approximately 17.5 million individuals have a chronic health conditions in the UK, with a higher prevalence in the older population (>75 years old) (Department of Health, 2001).

Moreover, chronic health conditions are more prevalent among the more socioeconomically deprived and the incidence of multi-morbidity (developing three or more chronic health conditions) is expected to rise in the ageing population (Department of Health, 2012).

Patients suffering from common chronic health conditions often complain of sleep-related problems (Shapiro, Devins & Hussain, 1993; Parish, 2009) such as having fewer hours of sleep and more unrefreshing sleep than healthy individuals, which in turn may trigger the symptoms of their illness (e.g. sleep complaint increases the



intensity of pain) (Parish, 2009). In a literature review on chronic insomnia, Ancoroli-Israel (2006) found that people with chronic health conditions usually experience sleep maintenance difficulty instead of sleep onset latency (e.g. difficulty falling asleep). Evidence suggests that insomnia rates are higher in people with medical and psychiatric conditions than in the general population (Katz & McHorney, 1998; Taylor et al., 2007).

Also, studies have examined the association between sleep problems (e.g. insomnia) and various chronic health conditions. For example, Foley, Ancoli-Israel, Britz, and Walsh (2004) examined the association between sleep-related problems and eleven different types of chronic health conditions (e.g. depression, heart disease, hypertension, arthritis, diabetes, osteoporosis, cancer etc.) in older adults (aged 55-84 years old) who have self-reported every night, or almost every night sleep-related problems (e.g. difficulty falling asleep, waking up too early, failing get back to sleep, feeling unrefreshed, experiencing breathing difficulties, having unpleasant feelings in the legs, etc.). The results showed that 83% of the participants had multi-morbidity of chronic health conditions (i.e. one or more chronic health condition) and about 25% of elderly adults (e.g. aged 65-84 years old) had four or more comorbid conditions. The findings also showed that different types of chronic health conditions are associated with different sleep problems. For example, patients suffering from heart disease, depression, pain and memory problems had symptoms of insomnia, whereas patients with obesity, diabetes, osteoporosis, arthritis, etc. experienced breathing pauses, daytime sleepiness, snoring or restless leg sleep-related problems. Furthermore, the authors concluded that sleep problems occur due to chronic health conditions and not to ageing *per se*.

Further evidence of this association is provided by Sutton, Moldofosky and Badley, (2001). They found that insomnia was related to particular types of chronic health conditions such as circulatory, rheumatic diseases, digestive and respiratory diseases, allergy and migraine) whereas age was not associated with insomnia. Also, a more recent community-based study found that insomnia was associated with a wide range of chronic health conditions. In particular, individuals with insomnia reported more heart disease, chronic pain, gastrointestinal problems, hypertension, breathing

difficulties, neurologic and urinary problems compared to individuals without insomnia (Taylor et al., 2007). Overall, these studies indicate that sleep-related problems are associated with various types of chronic health conditions.

In addition, the association between insomnia severity and comorbid chronic health conditions is well established in the research literature. For example, Katz and McHorney (1998) found that 16% of patients with chronic health conditions had severe insomnia and 34% had mild insomnia, whereas the remaining 50% of patients had sleep disturbance symptoms without meeting the study's criteria for insomnia. Katz and McHorney (1998) also found that the prevalence of both severe and mild insomnia endured, with 59% and 88% (with mild and severe insomnia respectively) of patients with chronic health conditions continuing to experience sleep problems at the 2-year follow up. However, like Foley et al. (2004) and Sutton et al. (2001) they found no significant association between insomnia and age.

Similarly, a more recent study that examined the association between insomnia severity and comorbid chronic health conditions showed that increased insomnia severity is independently correlated with an increased chronic health condition after controlling for psychiatric illnesses and psychiatric comorbidities (Sarsour, Morin, Foley, Kalsekar & Walsh, 2010). In addition, consistent with the research described above, evidence based on a review also suggests that people suffering from various chronic health conditions experience more severe and persistent symptoms of insomnia compared to people without chronic health conditions (Ancoroli-Israel, 2006).

Generally, these findings underline the association between sleep-related problems, insomnia and chronic health conditions and suggest that insomnia and other sleep-related problems are persistent in individuals with chronic health conditions. Evidence also suggests that patients with chronic health conditions are at greater risk of insomnia, although, due to the nature of the data, it is not possible to imply causality; therefore the relationship between sleep-related problems or insomnia and chronic health conditions is considered bi-directional.

Furthermore, various chronic health conditions may disturb sleep in different ways (McCrae & Lichstein, 2001b). Thus, the aetiology of insomnia based on the 3-P model (Spielman, 1986; Spielman & Glovinsky, 1991; Morin, 1993) as discussed previously (see section 2.1.2), can provide a theoretical framework for understanding the various factors that may contribute to and maintain sleep problems, and for selecting the best treatment for patients with chronic health conditions and sleep problems.

As such, the following sections review the most significant factors that may affect sleep problems in patients with various chronic health conditions that are considered the most relevant to the current study and to the treatment implemented in this study. Although, so far, the majority of evidence is based on patients with insomnia or other sleep-related problems, it is unclear whether there is a similar link between chronic health conditions and non-clinical sleep disturbance. Consequently, the current study will further explore this but first, it is critical to explore the psychological impact of living with sleep-related problems and chronic health conditions.

### **2.3. Factors contributing to and maintaining sleep problems in chronic health conditions**

There are many major concerns in the lives of individuals living with sleep disturbance including pain, depression, anxiety and stress symptoms, as well as sleep-related dysfunctional beliefs, maladaptive sleep habits and poor health quality of life. These areas will be considered and reviewed separately below.

#### **2.3.1. Pain**

Individuals with different chronically painful physical conditions (CPPCs) frequently experience sleep disturbance (Moldofsky, 2001; Smith & Haythornthwaite 2004; Ohayon, 2005). Some common CPPCs are irritable bowel syndrome (IBS),

headache, rheumatic diseases (e.g. arthritis, osteoarthritis), non-musculoskeletal disorders (e.g. back pain), somatoform disorder and fibromyalgia (Moldofsky, 2001). For example, Ohayon (2005) examined the relationship between insomnia and different CPPCs in community-based populations from five different European countries, including the UK, and found that 40.2% of people with insomnia symptoms had at least one CPPC and also that CPPCs were related to the difficulty or inability to sleep again after being awake, and they had a shorter duration of sleep. Another study among older patients with chronic health conditions found that daily bodily pain is related to symptoms of insomnia, unpleasant feelings, daytime sleepiness, etc. (Foley et al., 2004).

Power, Perruccio and Badley (2005) found pain to be a partially mediating factor in patients with arthritis and sleep problems. Moreover, the same study indicates that patients with arthritis but without pain reported higher insomnia symptoms compared to individuals without arthritis (17.1% vs. 9.4%). The authors also have controlled for other factors that may influence sleep, such as other chronic health conditions, sociodemographic characteristics and depression and stress factors and, therefore, they stated that it is unknown what other factors might influence sleep in patients with arthritis (Power, Perruccio & Badley, 2005).

The relationship between pain and sleep may be characterised as bi-directional, since pain may affect sleep and vice versa (e.g. Moldofsky, 2001; Smith & Haythornthwaite, 2004).

Taken together, such evidence supports the idea that pain is associated with sleep difficulties, or pain may be a mediating factor and/or other factors may influence sleep problems, particularly in patients with arthritis. Also, the nature of the relationship between pain and sleep difficulties is unclear (e.g. does pain causes sleep disorder and/or vice versa?). Since sleep-related problems are prevalent among individuals with CPPCs, the current study includes participants with CPPCs. However, because pain was not the focus of the study, it was not targeted as an outcome of the treatment intervention used here.

### **2.3.2. Depression, Anxiety and Stress**

Evidence suggests that various chronic medical conditions are associated with anxiety (Clarke & Currie, 2009; Harter, Conway & Merikangas, 2003; Scott et al., 2007) and depression (Clarke & Currie, 2009; Patten, et al., 2005; Scott et al., 2007). In particular, Smith Huang, and Manber (2005) suggest that patients with CPPC are more susceptible to depression and anxiety, mainly due to the physiological effects of the illness and its influence on their quality of life. Also, psychological factors are shown to be associated with sleep disturbance in patients with chronic health conditions (e.g. type 2 diabetes, myocardial infarction, affective or rheumatic disorders, chronic paraplegia) (Hyyppa & Kronholm, 1989).

Furthermore, the relationship between insomnia, depression and anxiety is widely known, since insomnia is a symptom of depressive disorder (NIH, 2005; Mai & Buysse, 2008) and generalized anxiety (Mai & Buysse, 2008). Individuals with insomnia may not meet the criteria for a major depression disorder or generalised anxiety. However, many individuals with insomnia report anxiety and/or depression (Morin, 1993). Evidence also indicates that the relationship between sleep-related problems (e.g. insomnia, sleep disturbance) depression (Sivertsen et al., 2012; Jansson-Frojmark & Lindblom, 2008; Spoormarker & van de Bout, 2005), and anxiety (Jansson-Frojmark & Lindblom, 2008; Spoormarker & van de Bout, 2005) is strongly bi-directional, as consistent with the findings from the pain research.

Further evidence suggests that insomnia may lead to mental health problems such as depression and anxiety (Ford & Kamerow, 1989; Bresleau, Roth, Rosenthan, Andreski, 1996; Taylor, Lichstein & Durrence, 2003; Baglioni et al., 2011). For example, a recent meta-analysis based on longitudinal epidemiological studies of the general population concluded that participants with sleep-related problems (such as insomnia symptoms e.g. difficulties initiating, maintaining sleep and non-restorative sleep) but with no depression have twice the risk of developing depression than those without insomnia symptoms (Baglioni et al., 2011).

Also, a community-based study shows that there is a strong association between depression, anxiety and insomnia. For example, a cross-sectional study by Taylor, Lichstein, Durrence, Riedel and Bush (2005) (with a combined  $n=722$ ) after controlling for confounding variables (e.g. gender and ethnicity, organic sleep disorder or medical disorders) showed that people with insomnia had higher levels of depression and anxiety compared to those without insomnia as measured by the Beck Depression Inventory (BDI; Beck, Ward, Mendelson, Mock & Erbaugh, 1961) and State Trait Anxiety (STAI; Spielberger, Gorsuch, & Lushene, 1970) respectively. In addition, a study of patients with multiple sclerosis (MS) found that depression and sleep disturbance, as measured by PSQI, are strongly associated (Merlino et al., 2009). Furthermore, an earlier study found a strong association between depression and insomnia in patients with various chronic health conditions (Katz & Horney, 1998). On the other hand, Morin, Gibson & Wade's (1998) study of patients with chronic pain found that poor sleepers reported slightly higher levels of anxiety and depression compared to good sleepers with chronic pain. However, the two groups did show statistically significant differences in anxiety and depression outcomes. The authors suggest that sleep disturbance is not certainly correlated with emotional disorder (Morin, Gibson & Wade, 1998). These findings are important, since they are not in line with previous studies that support the association between poor sleep quality, anxiety and depression.

With regard to the type of measurement in assessing depression and anxiety in individuals with insomnia, the BDI (Beck et al., 1961) or the Inventory of Depressive Symptomatology self-report (IDS-SR; Rush, Guillion, Basco, & Jarret, 1996; Trivedi et al., 2004) and STAI (Spielberger et al., 1970) measurement for anxiety are the main assessments in accordance with recommendations for standardized research assessment in a population with insomnia (Buysse et al., 2006).

Besides, stress is the most common precipitating factor in sleep disturbance (Morin, 1993; Morin, Rodrigue & Ivers 2003). For example, an early study by Healey et al. (1981) found that poor sleepers experience more stressful life events during the onset of insomnia compared to good sleepers and the occurrence of stressful events is

greater in comparison with previous or following years. Furthermore, a more recent study found that individuals with insomnia compared to good sleepers had similar experiences of minor stressful events. However, individuals with insomnia appraise both daily minor and major stressful events as more stressful, compared to individuals with good sleep (Morin, Rodrigue & Ivers, 2003).

In addition, another study among older adults with poor sleep and a greater amount of life stress had more sleep difficulties (e.g. difficulties falling asleep) but fewer early morning awakenings compared to those with less life stress and poor sleep (Friedman Brooks, Bliwise, Yesavage & Wicks, 1995). A further study found that highly stressful life events are associated with insomnia in individuals with chronic health conditions (Sutton et al., 2001).

In summary, patients with chronic health conditions are more predisposed to psychological symptoms such as anxiety or depression that may be related to the symptoms of their chronic health conditions. Also, insomnia is associated with depression, anxiety and the nature of the relationship is complex, since psychological distress may cause insomnia and vice-versa in a clinical and non-clinical population. Also, stress is common among individuals with insomnia and is associated with sleep-related problems.

### **2.3.3. Sleep-related Dysfunctional Beliefs**

More recently, cognitive factors (e.g. dysfunctional cognitions) have been shown to play a role in perpetuating insomnia (Morin, 1993; Morin, Stone, Trinkle, & Remberg, 1993) as previously stated (see section 2.1.2.), which, in turn, can elicit emotional arousal and cause sleep problems (Morin, et al., 1993). Since sleep-related dysfunctional beliefs are an important and critical factor in maintaining insomnia.

Morin (1994) developed a reliable and valid assessment for measuring sleep-related cognitions: the Dysfunctional Beliefs and Attitudes about Sleep scale (DBAS), (DBAS-30, followed by abbreviated versions; DBAS-10; Espie, Inglis, Harvey &

Tessier, 2000; DBAS-16; Morin, Valliers & Ivers, 2007), which is the most widely used measure in assessing sleep-related dysfunctional beliefs (Carney et al., 2010).

Studies have also examined whether individuals with good sleep or with insomnia encounter different dysfunctional beliefs and attitudes about sleep. For example, a cross-sectional study suggests that older individuals with insomnia ( $n=74$ ) uphold more rigid sleep-related dysfunctional beliefs and attitudes compared to individuals who self-report that they have good sleep ( $n=71$ ). Also, the authors suggested that an important clinical implication is to recognise these dysfunctional beliefs and to further target them for treatment (Morin, et al., 1993). Similarly, a larger cross-sectional study ( $n=382$ ) found that older adults with insomnia reported higher sleep-related dysfunctional beliefs (as measured by DBAS-10; Espie et al., 2000) compared to those people who sleep well (Ellis, Hampson & Cropley, 2007). Furthermore, the results showed that not all dysfunctional beliefs and attitudes about sleep (e.g. 'I need 8 hours sleep to feel refreshed and function well the next day') were shown to differ between people with and without sleep problems and this pattern of dysfunctional belief was not associated with chronic insomnia. However, the study used the brief version of the DBAS (e.g. DBAS-10) to assess sleep-related dysfunctional beliefs, which does not assess various sleep-related dysfunctional beliefs in the same depth as the original scales (Ellis, Hampson & Cropley, 2007).

Further studies have examined the degree to which sleep disturbance is associated with sleep-related dysfunctional beliefs in a clinical population and suggest a similar association to that seen in people with primary insomnia. For example, a recent cross-sectional study by Carney et al. (2007) examined whether those with primary insomnia and those with comorbid conditions (e.g. major depressive disorder, fibromyalgia etc.) have similar dysfunctional beliefs about sleep in comparison to those without sleep complaints. The results showed that sleep-related dysfunctional beliefs are persistent and similar in individuals with both primary or comorbid insomnia. Also, the comorbid insomnia patients generated higher total scores for maladaptive beliefs and attitudes compared to people with primary insomnia,



whereas individuals without sleep complaints reported relatively low total scores of dysfunctional beliefs.

Another cross-sectional study aimed to examine whether sleep disturbance in patients with chronic pain is associated with sleep-related dysfunctional beliefs. The results showed that patients with chronic pain and poor sleep ( $n=108$ ) as measured by PSQI endorsed higher levels of sleep-related dysfunctional beliefs compared to chronic pain patients with good sleep quality ( $n=48$ ) (Ashworth, Davidson & Espie, 2010). Furthermore, the authors found that chronic pain patients with poor sleep quality and good sleep quality had similar beliefs (e.g. 'I need 8 hours of sleep to feel refreshed and function well the next day'), suggesting similar results with previous studies in patients with primary insomnia (e.g. Ellis et al., 2007) (Ashworth et al., 2010).

Overall, it is clear that dysfunctional beliefs and attitudes about sleep may play a role in exacerbating sleep problems and perpetuating insomnia. Besides, the above findings showed a similar association between patients with primary insomnia and those with poor sleep quality and chronic health conditions (e.g. chronic pain). Also, the above studies showed that people with sleep problems encounter higher levels of dysfunctional beliefs compared to people without sleep problems.

A recent comprehensive cognitive model of insomnia was proposed by Harvey (2002), which explains the role of cognitions in maintaining insomnia. Specifically, Harvey's (2002) cognitive model proposes that negative cognitions (e.g. rumination or worry, such as not getting enough sleep and the effect of sleep disturbance on daily functioning), can trigger automatic arousal and emotional distress, which leads to higher levels of anxiety. As a result of these increased levels of anxiety, the individual becomes focused on sleep-related threats such as not getting enough sleep or failing to cope or function well during day. Consequently, these sleep-related threats trigger further worrying and distress, which leads to an increase in cognitive activity and arousal as well to a decrease in the likelihood of an individual sleeping. Furthermore, this model adds that individuals may adopt different behaviours, referred to as 'safety behaviours' (e.g. napping, drinking alcohol and avoiding difficult tasks) in order to lessen arousal. These 'safety behaviours' or maladaptive-

sleep behaviours will be discussed in more detail in the following section. It is possible that reductions in the negative beliefs associated with sleep may direct a reduction of maladaptive sleep habits and improve sleep (Edinger, Wholgemuth, Radtke, Marsh & Quillian, 2001).

Overall, Harvey's (2002) cognitive model suggests that cognitive processes are responsible for dysfunctional nighttime sleep processes and reduced daytime functioning, through excessive worry, emotional distress and physiological arousal.

In sum, the majority of the studies reviewed above were based on people with insomnia, suggesting that these individuals endorse higher dysfunctional beliefs compared to people without insomnia. One study (e.g. Ashworth et al., 2010) showed that patients with chronic pain and poor sleep quality reported higher levels of dysfunctional beliefs compared to patients with chronic pain and good sleep. Therefore, it is important to examine whether patients with non-clinical sleep disturbance and various chronic health conditions have high levels of sleep-related dysfunctional beliefs.

#### **2.3.4. Maladaptive Sleep Behaviours**

Behavioural theories propose that staying awake over an extensive time in the bedroom may result in stimulus dyscontrol, in which the bedroom environment might be associated with different behaviours other than sleep (Smith et al., 2005). This particular type of behaviour is very common among patients with chronic health conditions (Smith et al., 2005). For example, evidence suggests that patients with chronic pain spend unnecessary time in bed (e.g. to relax or nap) (Morin, Kowatch & Wade, 1989; Siebern, Suth & Nowakowski, 2012) or perform various daily routine activities in their bedroom or bed (e.g. snacking, reading and/or watching TV) (Morin et al., 1989). Morin et al. (1989) report that patients with chronic pain commonly engage in such behaviours in order to cope better with their physical condition, which in turn aggravates sleep disturbance. Also, a variety of other maladaptive behaviours such as alcohol intake as a sedative or increased caffeine

consumption (Smith et al., 2005) and medications are used in order to manage a coexisting disorder that may negatively affect sleep (Siebern et al., 2012).

Similarly, many individuals who have insomnia incidences may attempt to recompense for reduced sleep by adopting different maladaptive behaviours such as a) spending excessive time in bed (e.g. going to bed earlier and/or to getting out of bed later) which leads to more frequent awakenings, resulting in reduced sleep efficiency; and b) the practice of staying in bed while awake (i.e. the individual considers staying awake in bed a restful activity) which conversely leads to associating the bed and bedroom environment with arousal (Perlis, Giles, Mendelson, Bootzin, & Wyatt 1997). These two different types of maladaptive behaviour are interrelated and endorse one another (Perlis et al., 1997).

In summary, different maladaptive behaviours (e.g. poor sleep habits) may develop and they can aggravate and maintain sleep problems, consistent with theories on the aetiology of insomnia (e.g. Spielman, 1986; Spielman, Glovinski, 1991; Morin, 1993; Harvey, 2002). Therefore, it is essential that maladaptive behaviours of this kind are targeted in treatment.

## **2.4. The Impact of Sleep on Health-Related Quality of Life (HRQoL)**

According to the World Health Organization (WHO, 1946), health is defined as a “state of complete, physical, mental and social well-being, and not merely the absence of disease or infirmity”. In particular, to be considered healthy, one must not only be free of disease but also have a generally good quality of life. QoL is defined as: “an individual’s perception of their position in life in the context of the culture and values in which they live and in relation to their goals, expectations, standards and concerns” (WHO, 1998). In other words, this emphasises how individuals value their QoL based on their own perspective. These aspects of life are influenced by disease (Weaver, 2001). Consequently, the term ‘health related quality of life’ (HRQoL) highlights the impact of a disease or illness in relation to the

physical, functional and emotional or mental state and social wellbeing of an individual. HRQoL is an essential construct within healthcare since it measures the burden of disorder and it evaluates the effects of intervention on the daily functioning of an individual (Kyle, Morgan & Espie, 2010).

There are two main types of questionnaire for measuring HRQoL in people with sleep disorders: generic and disease-specific (Weaver, 2001). Generic questionnaires were developed to be used for a diverse population (e.g. with a wide range of diseases) (Weaver, 2001) whereas disease specific questionnaires were mainly developed for specific group of the population (Weaver, 2001).

Advantages of generic measurements are that they allow comparisons with other diseases, and evaluations of different activities and roles and can be easily used on a diverse population (Weaver, 2001). On the other hand, generic measurements lack deep evaluation (Weaver, 2001) and they are not considered sensitive enough measures for particular treatment outcomes (Reimer & Flemons, 2003).

The most commonly used generic measurements in sleep disorders are: a) the Medical Outcomes Study Short Forms (SF-36; Ware et al., 1992); b) the Sickness Impact Profile (SIP); Bergner et al., 1981); and c) the Nottingham Health Profile (NHP; Hunt et al., 1980) (Reimer & Flemons, 2003). In general, there is no gold standard generic measurement of HRQoL and sleep disorders (Reimer & Flemons, 2003) though the SF-36 survey has been extensively used in studies examining health-related quality of life and insomnia (Kyle et al., 2010; Buysse et al., 2006) and is a recommended and an essential measurement in assessing HRQoL in individuals with insomnia (Buysse et al., 2006).

Several studies, focusing mainly on the general/and or clinical populations, have examined the relationship between chronic insomnia and the impact of insomnia on HRQoL, showing that HRQoL is significantly reduced in people with insomnia. Leger, Scheuermaier, Philip, Paillard and Guilleminault (2001) found that people with severe insomnia scored lower on HRQoL as evaluated by the SF-36 survey, compared to people with mild insomnia and those with good sleep.

A more recent international (US, France and Japan) cross-sectional study found that individuals with insomnia had lower SF-36 (for both physical and mental components) levels across the three different countries, compared to people with good sleep. The authors concluded that chronic insomnia is associated with negative HRQoL (Leger et al., 2012). Similarly, another study found that inadequate sleep is associated with impairment in both physical and mental health domains (Strine & Chapman, 2005).

When assessing clinical populations, some cross-sectional studies have analysed data from an observational study (Medical Outcomes Study [MOS]) to examine the relationship between insomnia and HRQoL in patients with various chronic health conditions. For example, Katz and Horney (2002) found that insomnia is independently associated with poor HRQoL (e.g. after controlling for confounding variables such as anxiety, depression and medical comorbidities) in patients with various chronic health conditions (e.g. hypertension, myocardial infarction, diabetes, congestive heart failure and clinical depression). Furthermore, consistent with Leger et al. (2001) the authors found that a higher severity of insomnia signifies worse HRQoL.

A further line of evidence is aimed primarily at examining the association between poor sleep quality as measured by the PSQI and HRQoL (SF-36) in patients with various chronic health conditions. In this respect, Fortner et al. (2002) found that breast cancer patients with poor sleep quality had impaired HRQoL, mainly manifested in their ability to perform work and daily tasks, and they also reported low energy levels for daily activities. A more recent study found that patients with multiple sclerosis (MS) and poor sleep quality had a lower mental and health status as measured by the SF-36 survey when compared with good sleepers.

Poor sleep quality was found to be an independent predictor of HRQoL in patients with MS (Merlino et al., 2009). These findings suggest that poor sleep quality is associated with impaired HRQoL.

Finally, Manocchia, Keller and Ware (2001) examined whether sleep problems in patients with various chronic conditions (e.g. clinical depression, diabetes, congestive heart failure, arthritis, myocardial infarction, arthritis, back problems, etc.) are related to reductions in HRQoL. The authors found that individuals with different levels (mild, moderate and severe) of sleep-related problems had reductions in HRQoL compared to those with chronic health conditions without sleep problems. Furthermore, the results showed that severe sleep problems are associated with reductions in both work quality and productivity and with a higher use of mental and physical healthcare services (Manocchia et al., 2001).

Thus, insomnia presents a significant economic burden for both the individual and society (Mack & Rybarzyck, 2011) and it is also associated with increased healthcare utilisation in different countries (Leger, Guilleminault, Bader, Levy, & Paillard, 2002; Novak, Musci, Shapiro, Rethelyi, & Kopp, 2004; Simon & VonKorf, 1997; Daley, Morin, LeBlanc, Gregoire & Savard, 2009).

Overall these findings suggest that sleep problems, including insomnia and poor sleep quality, are associated with a negative impact in all domains of HRQoL as evaluated by the SF-36 survey among both the clinical and non-clinical population, as well as with increased related costs for the individual and society. Therefore, it is clear that early and effective treatment for sleep-related problems may prove beneficial for both society and individuals with such problems. Kyle et al. (2010) encourage future studies comprising of generic measurements of HRQoL or other equally valid measurements related to insomnia.

The reviewed literature shows conclusively that sleep-related problems are associated with psychological distress, higher dysfunctional sleep-related cognitions and significant impairment in HRQoL. Morin (2003) concluded that since insomnia is associated with significant detrimental health effects, an effective treatment for insomnia should not only aim to improve sleep but should also lead to clinical improvements, including better daytime functioning, reduced fatigue and improved mood, as well as quality of life. However, the current research tends to focus on insomnia rather than on non-clinical sleep disturbance.

Given the magnitude and complexity of the relationship between various factors and insomnia, it is possible that a similar relationship may exist in patients with non-clinical sleep disturbance.

Therefore, one of the aims of the current study is to explore if these factors are also pertinent in patients with chronic health conditions and non-clinical sleep disturbance. Nevertheless, gaining a greater understanding of the possible aetiology of factors potentially contributing to non-clinical sleep disturbance in populations with chronic health conditions does not provide useful information unless it can be used to derive meaningful interventions or treatments that could ultimately improve the psychological adjustment and health-related quality of life of these patients. Consequently, another aim of the current study is to investigate whether an intervention based on targeting the modification of some psychological factors could produce positive results that would bring about a meaningful and positive change in patients with chronic health conditions and with self-reported non-clinical sleep disturbance. Similar studies in the related field, in particular of patients with insomnia, have shown the effectiveness of treatment in sleep parameters and other clinically important outcomes. Evidence for the efficacy of this improvement will be reviewed in the subsequent sections. In general, there is a vast body of literature that suggests that the lives of individuals with insomnia and chronic health conditions can be improved by different types of treatments.

## **2.5. MANAGEMENT OF SLEEP PROBLEMS**

### **2.5.1. Treatments**

At first, the management of insomnia among patients with chronic health conditions aims to treat the primary condition (Kamel & Gammack, 2006; McCrae & Lichstein, 2001b) and comorbid insomnia is treated when the symptoms are severe or when the treatment for the primary condition is ineffective (McCrae & Lichstein, 2001b). Currently, there are various treatments available which aim to effectively manage insomnia as a comorbid condition. They include various types of pharmacological

treatments, complementary and alternative therapies (e.g. natural remedies and dietary supplements) and behavioural and psychological therapies (Kamel & Gammack, 2006).

The following section will provide a brief overview of the various treatments available and their effectiveness in managing sleep-related problems. Particular attention is given to the effectiveness of behavioural and psychological therapies and, more particularly, to Cognitive Behavioural Therapy (CBT) since it was the treatment implemented in the current study and it combines both psychological and behavioural therapies.

### **2.5.2. Pharmacological and complementary and alternative therapies**

Pharmacological treatments are mainly used for treating patients with insomnia (Currie, 2007; Morin, 2004; Koffel, Koffel & Gehrman, 2015) and other sleep-related problems (Currie, 2007) since they are widely available and provide rapid improvement (Mitchell, Gehrman, Perlis & Umscheid, 2012).

Meta-analyses have shown that pharmacological treatments are effective in managing insomnia in the short term (Nowell et al., 1997; Buscemi et al., 2007; Smith et al., 2002), and their use is associated with several adverse effects such as cognitive impairment, drowsiness headaches and dizziness (Holbrook, Crowther, Lotter, Cheng, & King, 2000; Buscemi et al., 2007).

Various natural remedies and dietary supplements are also promoted as sleep aids such as valerian that is most commonly used herbal remedy (Taibi, Landis, Petry & Vitiello, 2007) and dietary supplements such as melatonin hormone and alcohol with limited evidence around effectiveness (NIH, 2005). Several systematic reviews and meta-analyses have evaluated the effectiveness of valerian for sleep-related problems (e.g. Bent, Padula, Moore, Patterson & Mehling, 2006; Stevinson & Ernst, 2000; Taibi et al., 2007; Fernandez-San-Martin et al., 2010). However, the evidence is mixed and/or inconclusive with regard to its effectiveness for alleviating sleep-related problems. Similarly, a recent meta-analysis found that there is insufficient evidence to support the efficacy of other herbal remedies (Leach & Page, 2015). The



results show that further studies are essential, with more vigorous and robust methodological qualities to examine valerian as well as other herbal remedies and their relation to sleep-related problems.

In summary, since there is limited evidence of the effectiveness of herbal remedies and dietary supplements in managing sleep problems, it is unwise to consider them as effective treatments.

### **2.5.3. Behavioural and Psychological Treatments**

Another type of treatment used in the management of sleep-related problems includes behavioural and psychological therapies. Although pharmacological treatment is the most common method for treating insomnia, the positive effects have been shown to be effective only in the short term, and their use is frequently associated with a number of side effects as previously discussed. Hence, since insomnia emerges from a complex interaction of physiological, cognitive and behavioural factors (Spielman, 1986; Spielman & Glovinski 1991; Morin, 1993), evidence shows that it can be managed within behavioural or psychological therapies, which aim to change both the perpetuating and potential precipitating factors that contribute to insomnia (Morin, 2006), and explicitly to the aetiology of insomnia. These therapies are considered beneficial without any risk of intolerance or adverse effects (Trauer et al., 2015).

A growing body of evidence suggests that these treatments are effective in improving sleep patterns in patients with primary insomnia (Morin et al., 1999; Morin, Culpert, Schwartz, 1994; Murtagh & Greenwood, 1995). For example, Morin et al. (1999) found that 70%-80% of patients treated with behavioural or psychological therapies showed improvement in sleep. Furthermore, evidence suggests that behavioural treatments are more effective than pharmacological treatments. Morin, Colecchi, Stone, Sood and Brink (1999) found that cognitive-behavioural therapies led to longer-term improvements than pharmacological treatments in patients with primary insomnia. Also, a meta-analysis found that both pharmacological and behavioural treatments are effective, with behavioural treatment being more effective at reducing

sleep latency (Smith et al., 2002). Recent evidence also suggests that patients who use medication show a higher preference for non-pharmacological treatment to treat their sleep problems (Omvik, Pallesen, Bjorvatn, Sivertsen & Havik, 2010).

Since non-pharmacological treatments are gaining increasing attention and have been shown to be as effective as pharmacotherapy, and more effective in the long-term, this chapter aims to introduce the most commonly used non-pharmacological therapies for the management of insomnia.

Initially, in the 1970s and 1980s, insomnia was commonly treated by stimulus control therapy (SCT: Bootzin, 1972; Bootzin, Epstein & Wood, 1991), paradoxical intention and relaxation-based therapies (RT) (Bootzin & Epstein, 2011). Later other behavioural therapies for insomnia were introduced such as the sleep restriction therapy (SRT: Spielman, Saskin & Thorpy, 1987; Glovinski & Spielman, 1991). Further treatments were developed such as educational sleep hygiene (SH: Hauri, 1991) and cognitive therapy (Morin, 1993), and more recently a hybrid approach was developed, most commonly known as cognitive-behavioural therapy (CBT) (Morin, 1993), the approach endorsed in the current study. Each of these therapies is roots in different theoretical perspectives (behavioural, educational or cognitive) that target different aspects of insomnia and are shown to be effective, either as single-treatment methods or in combination with various other techniques. The subsequent section provides an overview of the different therapies for the management of insomnia. It contains a brief description of their theoretical backgrounds, along with the supporting scientific evidence, with a view to providing a comprehensive justification for the selection of CBT-I and for the decision to administer CBT-I in the form of a self-help booklet in the current study.

## **2.6. Behavioural Therapies for Insomnia**

### **2.6.1. Theoretical background of Behavioural Therapies**

Behavioural therapies for the management of insomnia include: Stimulus Control Therapy (SCT: Bootzin, 1972; Bootzin et al, 1991), Sleep Restriction Therapy (SRT: Spielman et al., 1987; Glovinski & Spielman, 1991), Sleep Hygiene Therapy (SHT: Hauri, 1991) and relaxation-based treatments (e.g. imagery relaxation) (Morin, et al., 2006), which additionally target some cognitions (e.g. cognitive arousal) (Morin, 2004).

SCT (Bootzin, 1972; Bootzin, et al., 1991) is theoretically underpinned by learning theory (Ebben & Spielman, 2009) and is grounded in the principle that certain sleep disturbances are behaviourally habituated (Martin et al., 2000). For example, in SCT, individuals learn to re-associate or improve the association between sleep and stimulus conditions (e.g. bed, bedtime and bedroom) (Morin, 1993). Individuals are directed to restrict all other behaviours/activities that occur in the bedroom, other than sleep and sex, only retiring when they are sleepy. If they find themselves unable to sleep after 15 or 20 minutes they must leave the bedroom until they are sufficiently sleepy. Also SCT demands that individuals establish a pre-sleep routine every night and refrain from napping during the day (Currie, 2007; Trauer et al., 2015). SCT might be more suitable for patients with a counter-productive and inconsistent sleep schedule (Edinger & Whohlgemuth, 1999).

SRT (Spielman et al., 1987; Glovinski & Spielman, 1991) is a different behavioural therapy, and its rationale is that an extensive time spent in bed perpetuates insomnia. Consequently, as the name implies, it demands that the individual stay in bed only when sleeping and leave the bed when awake (Spielman Saskin & Thorpy, 1987). For example, if an individual with insomnia sleeps for only 5 hours out of 8, it is recommended that the time in bed to be reduced to 5 hours, referred to as the 'sleep window' which can be adjusted weekly until optimal sleep efficiency is achieved (Morin, 2004). In order to achieve the targets of SRT, sleep efficiency is computed by dividing total sleep time by the total time in bed multiplied by 100. The target for

an individual with insomnia would normally be 85% (Morin, 2004). If an individual's sleep efficiency is below 80% the therapy recommends reducing the sleep window by 15-20 minutes. In cases where, sleep efficiency is above 90% the sleep window can be increased by the same amount (Morin, 2004). Consequently, SRT aims to reduce sleep deprivation, which endorses quicker sleep-onset, better sleep efficiency with fewer incidences of waking during the night (Morin et al., 1999; Morin, 2004).

Both SCT and SRT aim to reduce the behavioural factors that prolong or maintain insomnia (Stepanski & Perlis, 2000).

SHT (Hauri, 1991) is an educational-behavioural oriented therapy that targets lifestyle habits and environmental factors that inhibit sleep (Edinger & Means, 2005). Specifically, SHT educates individuals about healthy sleep behaviours (e.g. that they should exercise regularly, limit nicotine, caffeine, and, alcohol consumption and eat light meals before bedtime), sleep-promoting environmental conditions (e.g. room temperature, limited noise, a dark room and a comfortable sleep environment) (Edinger & Means, 2005; Stepanski & Wyatt, 2003).

Relaxation-based treatments are considered alternative behavioural therapies for insomnia. These techniques are based on the theory that individuals with insomnia usually experience high levels of physiological and/or cognitive arousal during the day and at night (Morin et al., 1999) and they can be applied to individuals who are relatively anxious about not being able to sleep (Edinger & Wholgemuth, 1999).

For example, progressive muscle relaxation (PMR), autogenic and biofeedback relaxation techniques aim to reduce physical arousal or muscle tension, while other relaxation techniques such as imagery training, meditation and thought stopping are mainly focused on eliminating cognitive arousal (Morin, 2004).

Before deciding on the optimal intervention, it is best to consider the effectiveness of the interventions. The following section reviews the effectiveness of behavioural therapies either as single therapies or in combination in patients with primary insomnia or comorbid insomnia.

### **2.6.2. Effectiveness of Behavioural Therapies**

Evidence suggests that behavioural-based therapies like SCT and SRT are effective as single-therapies for patients with primary insomnia. For example, meta-analysis data and reviews suggest that SCT is empirically supported as an effective single therapy (e.g. Morin et al., 1994; Morin et al., 1999) and can be considered as a recommended treatment for insomnia (Morgenthaler et al., 2006).

Also other studies have examined the effectiveness of SRT and showed that SRT is an effective treatment for sleep problems (Spielman et al., 1987; Friedman, Bliwise, Yesavage & Salom, 1991). Similarly, meta-analysis data found that SRT is an effective single therapy (e.g. Morin et al., 1994). Furthermore, in accordance with the Practice Parameters of the Standards of Practice Committee, SRT can be recommended as a single therapy (Morgenthaler et al., 2006).

On the other hand, some evidence suggests that SHT is not effective as a single intervention (Morin et al., 1994) and is not recommended as a single therapy for insomnia (Morgenthaler et al., 2006) because there is limited evidence.

However, sleep hygiene is considered an essential part of treating insomnia by promoting healthier sleep hygiene practices (Morin, 1993). Since environmental and lifestyle factors may influence sleep disturbance (Morin, 1993; Morin, 2004), poor sleep hygiene may be perceived as a perpetuating factor (Stepanski & Wyatt, 2003).

Also, further development of these approaches allow for combined behavioural interventions.

Single-case studies indicate the effectiveness of combined behavioural interventions in patients with chronic health conditions and sleep problems. For example, three single case studies included a patient with haemophilia disorder (e.g. Varni, 1980), cancer (e.g. Stam & Bultz, 1986) and depression (Morin, Kowatch & O'Shanick (1990). Specifically, Varni (1980) examined the effectiveness of a behavioural intervention, which was an amalgam of various techniques such as PMR, meditative breathing, cognitive refocusing and stimulus control, and found that this combination of techniques was related to a significant increase of hours per night with continuous sleep. Stam & Bultz (1986) found that a behavioural intervention, based on

progressive muscle relaxation and imagery training significantly improved total sleep time for up to 12-months and decreased sleep latency. Finally, Morin et al. (1990) found that SRT was effective in increasing total sleep time in a depressed patient and these improvements were maintained at a 4-month follow-up.

In addition, Morin, et al. (1989) conducted a small sample size ( $n=3$ ) study to examine the efficacy of a behavioural combination treatment consisting of SCT and SRT for patients with chronic pain using a multiple baseline design. Each participant showed significant improvements in both subjective and objective measures of sleep patterns at post-treatment and follow-up.

The first randomised behavioural study was conducted by Cannici, Malcom and Peek (1983) and it showed that muscle relaxation was effective in improving sleep latency and the total sleep time in cancer patients.

A more recent study randomized older adults with comorbid medical (mainly chronic pain) or psychiatric disorders (e.g. depression) to a treatment intervention, consisting of four sessions of sleep hygiene instructions, relaxation and an SCT group or a control group. The results showed significant subjective sleep improvements as measured by sleep diary (e.g. time awake after sleep onset, sleep efficiency and sleep quality) at post-treatment and at a 3-month follow-up. However, no significant differences were found for anxiety and depression outcomes (Lichstein, Wilson & Johnson, 2000).

Overall, the above evidence shows that behavioural therapies are promising and effective for treating insomnia in both non-clinical and clinical populations as single therapies or when used in combination. However, studies within a clinical population (including patients with chronic health conditions such as cancer, pain, haemophilia etc.) have some important pitfalls in their designs with small sample sizes, and other issues that limit the generalisability of the findings.

As discussed previously, evidence shows that sleep problems are perpetuated due to the influence of various behavioural and cognitive factors. Consequently, it can be argued that the above therapies are inadequate, since they fail to take into account – and/or they do not directly address – all the perpetuating factors (e.g. dysfunctional beliefs) that affect sleep (Edinger & Means, 2005).

Even though some relaxation therapies include some cognitive relaxation methods, as discussed above, they are predominantly, relaxation-based therapies, which aim to reduce continued arousal and sleep-related anxiety by not targeting cognitive factors that maintain sleep problems (Edinger & Means, 2005).

### **2.6.3. Cognitive Behavioural Therapy for Insomnia (CBT-I)**

So far, a variety of treatments have been discussed, such as pharmacological, complementary/alternative (e.g. herbal remedies), together with a variety of behavioural therapies (e.g. stimulus control, sleep restriction, relaxation therapies and sleep-educational hygiene). Pharmacological therapies are associated with side effects and shown to be effective in short-term; on the other hand, complementary therapies are limited evidence-based and behavioural therapies shown to be effective but they do not directly target all that factors that maintain sleep problems.

Therefore, in order to overcome the limitations of behavioural therapies, and by taking into account the aetiology of insomnia (see section 2.1.2.). Morin (1993) proposed cognitive therapy that encourages patients to re-evaluate their thoughts concerning insomnia, and to understand of its causes and consequences.

Particularly, the main aim of cognitive therapy is to give patients a more realistic perspective on their sleep related behaviours by using the cognitive restructuring techniques of reappraisal, reattribution and decatastrophizing (Morin, 1993). For example, individuals are instructed to identify cognitions related to dysfunctional beliefs, challenging their validity and replacing sleep-related dysfunctional cognitions with more adaptive and reasonable ones altering interpretations of sleep and sleep related behaviours (Morin, 1993). Subsequently, cognitive restructuring techniques were included in the behavioural methods to form a more comprehensive treatment approach to insomnia, known as Cognitive Behavioural Therapy for insomnia (CBT-I) (Morin, 1993; Morin, 2004). The main aim of CBT is to target those factors that perpetuate insomnia (Morin, 1993; Morin, et al., 1994; Siebern et al., 2012).

Specifically, CBT-I aims to change maladaptive sleep habits and dysfunctional beliefs and attitudes about sleep that may trigger and support anxiety, and to educate individuals about healthier sleep habits and lifestyle practices (Morin, 1993). A typical CBT-I protocol integrates three distinct key components: a) behavioural (e.g. combining SCT and SRT), b) cognitive (e.g. cognitive restructuring techniques) and c) educational (e.g. SH) as outlined and discussed above, together with an optional medication-withdrawal component for individuals who rely on sleep medication (Morin, 1993). With regards to medication-withdrawal, the aim is to help the individual to gradually withdraw from sleep medication (Morin, 1993). In addition, to these components, relaxation-based therapies have been assimilated into the package of CBT-I (Morin, 2004; Bootzin & Epstein, 2011). Consequently, incorporating various methods is valuable and can enhance the outcome (Morin, et al., 1999; Morin, 2006) since any single technique may partially address the sleep problem as a whole (Lacks & Morin, 1992). Also a more recent systematic review (which included randomized controlled studies) showed that CBT is more effective than any single component (e.g. stimulus control, relaxation-training, etc.) (Wang, Wang & Tsai, 2005).

CBT is usually delivered in the form of face-to-face sessions, either individually or in the form of a group (Pigeon, 2010b) in weekly sessions that continue over a 6 to 8-week period (Pigeon, 2010b). Initially, CBT was a treatment for patients with primary insomnia (Rybarczyk et al., 2005) and to date it has been systematically assessed in a healthy population with insomnia. The National Institute of Health (2005) concluded that CBT is at least as effective as medication for the short-term treatment of insomnia, and its beneficial effects may last longer than pharmaceutical solutions, extending beyond the end of the period of active treatment. Consequently, CBT is currently the best treatment for insomnia (Espie, 1999; Espie, 2009; NIH, 2005; Mack & Rybarczyk, 2011).



Whereas, until recently, studies in the current area used to exclude individuals with comorbid insomnia, and as previously discussed (see section 2.5.1.) the initial approach to managing insomnia was to treat the primary condition, since initially it was believed that medical or psychiatric illness were the main cause of insomnia among chronically ill patients with insomnia. However, the evidence considered above suggests that these factors were not necessarily the main cause of insomnia among individuals with chronic health conditions and sleep problems. The reviewed evidence suggests that other factors, such as psychological, are shown to be associated with insomnia and the evidence also suggests that patients with comorbid insomnia may develop several maladaptive behaviours (both cognitive and behavioural) that contribute to insomnia (Stepanski & Rybarczyk, 2006). In addition, earlier behavioural studies (e.g. Varni, 1980; Stam & Bultz, 1986; Morin et al., 1990) despite their limitations as stated previously (see section 2.6.2) showed that behavioural therapies could be considered beneficial for the treatment of comorbid insomnia.

Therefore, taking into account the cognitive and behavioural factors that play a role in the development and maintenance of comorbid insomnia and by following the promising evidence regarding the effectiveness of CBT-I in a healthy population, more recent, studies have examined the effectiveness of CBT-I in patients with comorbid insomnia. Exciting evidence has shown the effectiveness of behavioural and cognitive therapies for patients with chronic health conditions and sleep problems (e.g. Smith et al., 2005; Morin, et al., 2006; Stepanski & Rybarczyk 2006; Geiger-Brown et al., 2015). The section below provides a review of studies examining the effectiveness of CBT-I for patients with various chronic health conditions and sleep problems.

### **2.6.3.1. Effectiveness of Multicomponent CBT-I for patients with Chronic Health Conditions**

Currie, Wilson, Pontefract and deLaplante (2000) conducted the first CBT-I study on patients with chronic pain and insomnia. The supported hypothesis of the intervention was that behavioural factors play a role in exacerbating or maintaining sleep problems in patients with chronic painful conditions. Consequently, altering these maladaptive behaviours can promote sleep improvements, despite the fact that pain is not targeted (Currie et al., 2000). Patients were randomly assigned to either the CBT 7-week group intervention or to the waiting-list (WL) group. The results showed that the CBT-I 7-week group reported significant improvements in several sleep parameters (e.g. sleep quality, sleep onset latency, sleep efficiency and wake time after sleep onset) as measured by self-report measures (e.g. sleep diary and PSQI) and also showed less motor activity as measured by an objective measure (e.g. actigraphy). Also these sleep improvements were maintained at the 3-month follow-up assessment. However, no significant reductions were found in depression following the completion of the intervention. Overall, this study showed that group CBT-I is effective in improving sleep in patients with chronic pain but not in reducing emotional distress (e.g. depression).

A later study was conducted by Edinger, Wohlgenuth, Krystal & Rice (2005) in patients with fibromyalgia who either received 6-weekly CBT-I individual sessions, sleep hygiene, or treatment as usual care control (UCC). The results showed that participants in the CBT-I group showed a greater improvement (50%) in their nocturnal wake time than the SH (20%), and UCC (3.5%) groups, as measured by sleep logs. Also the CBT-I group showed reduced insomnia severity symptoms and improved mental well-being and mood compared to the UCC group. The SH group showed positive outcomes in pain and well-being. In other words, the current findings may be interpreted as an indication that the CBT-I intervention has a greater effect in improving sleep as well a greater effect in changing other clinical outcomes related to sleep (e.g. mood).

In another randomized trial, patients with non-malignant pain were randomized to either an 8-week individual CBT-I group or to a control group. CBT-I was effective in improving sleep (as measured by sleep diary and ISI), whereas no differences were found in terms of mood measures (e.g. depression as measured by BDI) between the two groups (Jungquist et al., 2010).

Further study found support for the efficacy of CBT-I (e.g. tailored for cancer patients) in patients with cancer, concluding that the implementation of CBT-I improved subjective sleep indices, reduced levels of depression and anxiety, and improved global quality of life (disease-specific questionnaire) (Savard, Simard, Ivers & Morin, 2005). Similarly, Qunsel, Savard, Simard, Ivers, and Morin (2003) found that CBT-I was effective in improving sleep in women with non-metastatic breast cancer. The results also showed a reduction in depressive symptoms, physical fatigue and improved quality of life (e.g. global and cognitive dimensions) as measured by an HRQoL disease-specific questionnaire. However, no significant differences were found in anxiety.

Another study randomized patients with chronic obstructive pulmonary disease (COPD) either to a 6-week CBT-I intervention or to a 6-week wellness education (WE) (e.g. including education on how the lungs work, medications, breathing techniques, etc.). The CBT-I group showed significant improvement in insomnia severity, global sleep quality, wake after sleep onset, sleep efficiency, sleep-related dysfunctional beliefs and fatigue, whereas the WE groups showed reduced levels of anxiety and depression (assessed using tension anxiety and depression-dejection). These findings indicate that CBT-I is an effective treatment in improving overall sleep quality and other sleep-related outcomes (Kapella et al. 2011).

Additional studies have examined the effectiveness of CBT-I in patients with mixed chronic health conditions. Rybarczyk, Lopez, Benson, Alsten, and Stepanski (2002) assigned older adults with chronic health conditions (e.g. coronary artery disease, osteoarthritis and type II diabetes) either to classroom CBT-I including relaxation techniques, to home-based video audio relaxation treatment (HART) or to delayed control. The CBT group experienced significant improvements in subjective sleep

patterns (sleep diary) and a reduction in sleep-related dysfunctional beliefs. Also, sleep improvements were maintained at a 4-month follow-up. Similarly, the HART group showed sleep improvements, but the CBT group showed greater improvements. Sleep improvements were not related to improved health-related quality of life, pain and anxiety.

In a later study, Rybarczyk et al. (2005) included a different group of older adults (55 years and older) with osteoarthritis, coronary artery disease or pulmonary disease, and participants were randomly assigned to either 8 weekly 2-hour CBT-I classroom sessions or stress management and wellness training (SMW). The CBT group showed significant sleep improvement and reductions in sleep-related dysfunctional beliefs compared to the SMW group. However, no significant differences were found for mood, pain and health-related quality of life.

Overall, based on the evidence emerging from the above studies, we may conclude that CBT-I is an effective treatment for comorbid insomnia associated with various chronic health conditions. However, despite its effectiveness, CBT-I is an expensive treatment option and is not easily accessible as it is only available through face-to-face sessions with a specialist (Espie, 2009; Perlis & Smith, 2008). Other barriers in terms of CBT implementation include time and a lack of CBT-trained therapists (Morin & Benca, 2012; Perlis & Smith, 2008; Edinger, 2009). Due to these barriers, only few a patients with insomnia receive CBT to manage their problems (Espie, 2009). In terms of its cost-effectiveness, CBT-I group therapy is a cost effective method compared to individual therapy for the management of insomnia (Bastein, Morin, Quillet, Blais & Bouchard, 2004). However, this mode of treatment still shares constraints, as with individual therapy, in terms of practical issues such as geographical restraints and transport costs (Bastein et al., 2004).

## **2.7. Stepped Care Model: Self-help CBT-I**

Recently Espie (2009) proposed a 5-level stepped care model: ‘a health technology solution for delivering CBT as the first line of insomnia treatment’ to increase resources and improve clinical care for individuals with insomnia. The five levels of this model differ in the way they provide CBT-I and cost, although the treatment shares the same context. For example, individuals initially begin with less restrictive treatment (e.g. CBT is provided in the form of self-help) and thereafter individuals may progress to more intensive treatment (e.g. group CBT delivered by a trained therapist; then followed by a graduate psychologist, followed by a clinical psychologist and finally by an expert at a behavioural medicine clinic).

Espie (2009) recommends self-help (SH) CBT-I as the initial treatment step of the 5-level stepped care model, since it is the least restrictive evidence-based treatment to generate meaningful health benefit, it can be easily administered, it is cost-effective and can provide value to a significant proportion of patients while not causing any adverse risk effects.

Self-help (SH) treatments are described as standardized psychological treatments that patients can self-administer in their own time and at their own pace (van Straten & Cuijpers, 2009) and can be applied through various media such as a booklets (bibliotherapy), CD-ROM, the Internet or the media (Espie, 2009; van Straten & Cuijpers, 2009). Compelling evidence from meta-analysis data suggests that SH treatments based on behavioural therapies and CBT are effective as face-to-face treatments but with small to moderate effects, which means that SH treatments cannot take the place of therapist-led CBT interventions (van Straten & Cuijpers, 2009) but may be considered effective enough to be integrated into stepped care at the initial entry level (van Straten & Cuijpers, 2009; Ho et al., 2015).

The following section reviews the effectiveness of CBT-I in the form of self-help for patients with insomnia and comorbid insomnia.

### **2.7.1. Effectiveness of CBT-I in the form of Self-Help (SH)**

Early studies have established the effectiveness of the CBT-I SH booklet for patients with primary insomnia. Mimeault and Morin (1999) examined the efficacy of a CBT-I SH booklet with and without professional guidance in adults ( $n=54$ ) with primary insomnia. Participants were randomly assigned either to the CBT-I SH booklet with or without professional guidance, or to the waiting list (WL) group. At post treatment, both CBT-I SH groups showed significantly improved sleep, reduced anxiety, depressive symptoms and sleep-related cognitions compared to the WL group and these improvements were maintained over three-months. In addition, at the end of the intervention the CBT-I group with minimal professional guidance showed greater improvements in sleep outcomes, though these improvements disappeared at the 3-month follow-up. The current study suggests that CBT-I in the form of a SH booklet with minimal professional guidance (or indeed with none) is an effective approach for patients with primary insomnia.

Another study showed that CBT-I in the form of self-help does not lead to significant sleep improvements (as measured by sleep diary). On the other hand, the results showed that CBT-I self-help is effective in reducing sleep-related dysfunctional beliefs, depressive symptoms and HRQoL (e.g. mental component). In sum, the authors suggested that CBT-I self-help benefits individuals in coping with insomnia (van Straten, Cuijpers, Smit, Spermon, & Verbeek, 2009). Further study based on community sample (without screening or excluding any participants with medical or psychiatric comorbidities) found that the CBT-I intervention which included six self-help booklets provided by mail every week (with an optional free phone line for further support), was effective in improving subjective sleep quality and reducing symptoms of insomnia severity, anxiety and depression. Subjective sleep improvements were maintained at a 6-month follow-up, whereas improved levels of anxiety and depression at follow-up disappeared (Morin, Beaulieu-Bonneau, LeBlanc & Savard, 2005). CBT-I in the form of self-help is effective in improving sleep any psychological distress among diverse group of participants.

Few studies have examined the effects of the CBT-I SH booklets for patients with comorbid insomnia in patients with mixed chronic health conditions. For example, a recent study in the UK by Morgan, Gregory, Tomeny, David, & Gascoigne (2012) examined the effectiveness of a 6-week CBT-I SH booklet with access to telephone support (from expert patients) in older adults ( $\geq 55$  years old) in primary care reporting insomnia symptoms associated with chronic health conditions (e.g. cancer, osteoarthritis, diabetes mellitus, chronic obstructive disease, fibromyalgia, coronary heart disease and hypertension, depression and Parkinson's disease). Participants showed significant improvements in sleep quality and reduced symptoms of insomnia and these improvements were maintained in the long term. However no significant differences were found in daytime fatigue severity.

Another study by Rybarczyk, Mack, Harris and Stepanski (2011) aimed to compare two different methods of CBT-I SH (e.g. CBT-I SH booklet vs. CBT-I multimedia version) based on the same content with weekly telephone support in older adults (aged 55 and older) ( $n=106$ ) with osteoarthritis ( $n=33$ ), coronary disease ( $n=33$ ) or no significant medical conditions ( $n=40$ ). Findings showed that CBT-I SH interventions were effective in improving sleep measures and dysfunctional beliefs and attitudes about sleep at post treatment. At one-year follow-up ( $n=86$ ), the results showed that sleep improvements were sustained, showing effectiveness in the long term. The authors concluded that CBT-I SH with minimal support has the potential to be equally effective as individual treatment and is cost-effective for patients with insomnia and comorbid insomnia.

Jermelov, Lekander and Blom (2012) compared the effects of a 6-week CBT-I booklet with or without therapist support to a waiting list control (WLC) in patients with comorbid insomnia. Both CBT-I groups showed improved sleep quality and reduced insomnia severity symptoms compared to the WLC. The CBT-I group with telephone support also showed reduced dysfunctional beliefs about sleep, perceived stress, daytime fatigue and reduced sleep-related behaviours when compared to the WLC. This study also showed that improved sleep changes were higher in the group with telephone therapist support at post-treatment and at a 3-month follow-up.

Overall, these results suggest that CBT-I with therapist support leads to greater sleep improvements and improve coping with insomnia.

A recent study (Casault, Savard, Ivers & Savard, 2015) examined the effectiveness of a minimal 6-week CBT-I SH booklet accompanied by a brief telephone consultation on patients with cancer and acute insomnia (e.g. insomnia less than 6 months). The minimal multimodal CBT-I SH booklet appeared to improve sleep parameters, reduced anxiety and depression and significantly reduced maladaptive sleep habits and dysfunctional beliefs and attitudes about sleep and improved subjective cognitive functioning of the QoL. Also, the current study shows that these therapeutic improvements were maintained for six months. However, no significant differences were found for fatigue or global quality of life.

Finally, Rybarczyk, Lopez, Schelble and Stepanski (2005) examined the effectiveness of a different method of delivery of CBT-I SH in older patients with comorbid insomnia, a home CBT-I based video with weekly telephone support. The study sample was older adults with comorbid medical conditions (e.g. hypertension, coronary artery disease, osteoarthritis, type II diabetes, myocardial infarction etc.). The results showed that participants, compared to controls, showed significant improvement in self-reported overall sleep quality, dysfunctional beliefs and attitudes about sleep, mood, and HRQoL (e.g. daytime and social functioning and energy vitality). The current study suggests that home-based video is a relatively beneficial and cost-effective treatment.

In conclusion, CBT-I SH for patients with chronic health conditions and insomnia seems encouraging, since compelling evidence shows it to be effective in alleviating sleep, with some evidence suggesting that CBT-I is effective in reducing psychological distress (e.g. anxiety, depression and stress), dysfunctional beliefs and maladaptive sleep habits and improved HRQoL. Furthermore, evidence suggests that CBT-I SH as an initial treatment step of the stepped care model is considered an advantageous approach as a starting treatment since it is a less complex therapy, readily available and more cost-effective.



Furthermore, it is important to remember that the majority of the research relates to clinical sleep disturbance or insomnia. As argued earlier, it is unclear whether similar treatment benefits will be found in a non-clinical sleep disturbance population.

Therefore, the current study aims to make a further contribution by examining the effectiveness of CBT-I in the form of self-help for patients with non-clinical sleep disturbance and various chronic health conditions for sleep patterns as well as the effect of this treatment on anxiety, depression and stress symptoms, sleep-related dysfunctional cognitions and HRQoL.

## **2.8. Summary of the existing literature**

Insomnia is the most prevalent sleep disorder and, clinically, is referred to as difficulty in initiating or maintaining sleep, and/or poor quality of sleep. Evidence shows that people who have chronic health conditions are more likely to have sleep problems, in particular insomnia, than a healthy population. Within the context of chronic health conditions, sleep problems can be influenced by various factors such as pain, or psychological and behavioural factors. We also know from the literature that these factors may have a reciprocal relationship among patients with various chronic health conditions and insomnia since there is no clear direction of their causality (e.g. whether pain affects sleep or vice-versa). Also, insomnia is associated with a reduced health-related quality of life in patients with chronic health conditions and increased health care costs. Overall, the evidence suggests that sleep problems, especially insomnia, are common among patients with various types of chronic health conditions and may negatively affect symptoms of their condition or conversely, the symptoms of their chronic health condition may further trigger and maintain sleep problems.

Various treatment options are available for the management of sleep problems including pharmacological and herbal remedies and dietary supplements. Pharmacological treatments prove to be effective in the short term, whereas their long-term use is associated with serious adverse effects.

However, the evidence is limited regarding the effectiveness of herbal remedies and dietary supplements. Over time, a variety of alternative treatments for sleep problems has become available, focusing on targeting factors that precipitate and perpetuate sleep problems, such as psychological factors. Initially, the most commonly applied interventions were behavioural-oriented interventions, including stimulus control therapy, a variety of relaxation therapies, sleep restriction and educational sleep hygiene therapy in treating sleep problems.

One of the difficulties of such interventions is that they are relatively restrictive approaches since they do not have a framework that allows us to entirely address the various factors (e.g. dysfunctional cognitions) subsumed in the 3-P model (Spielman's 1986; Spielman & Glovinski, 1991; Morin, 1993). As a result, a more hybrid and comprehensive approach has been developed, known as cognitive behavioural therapy for insomnia (CBT-I) that addresses both behaviours (e.g. maladaptive sleep habits) and cognitions (e.g. dysfunctional beliefs about sleep) that may play a role in triggering and maintaining sleep problems. CBT-I has been considered the treatment of choice for improving sleep in patients with primary insomnia and recent studies have shown its effectiveness in patients with various chronic health conditions. Also, Morin (2003) suggests that, since insomnia is associated with morbidity, an effective treatment should not only improve sleep but also improve psychological adjustment and quality of life. The research reviewed above has provided mixed findings in relation to psychological adjustment (e.g. depression, anxiety) and improved health-related quality of life. On the one hand, some studies indicate that CBT for insomnia is effective in reducing anxiety, depression and improving health-related quality of life. On the other hand, other findings suggest that CBT is not effective in improving such outcomes. Although, the results are mixed in relation to psychological adjustment and improved health related quality, CBT is effective in improving sleep. A major barrier to the application of CBT is that it has limited accessibility in practice, due to the lack of trained CBT therapists and the associated high costs of delivering such treatment.

Recently, Espie (2009) proposed the 5-level stepped care model for CBT-I to deal with these barriers. Espie's (2009) model recommends the delivery of CBT in the form of self-help as a first option in stepped care. Recent evidence shows that CBT-I SH is an effective and applicable treatment both in clinical and non-clinical populations with insomnia.

### **2.8.1. Problem with the literature and scope of the study**

The existing literature tends to focus particularly on individuals with clinical sleep disturbance or insomnia showing the complexity of the relationship between insomnia and psychological factors (e.g. depression may cause insomnia or vice versa), sleep-related dysfunctional beliefs and impaired health-related quality of life. However, individuals with non-clinical sleep disturbance and chronic health conditions have been largely overlooked. Therefore, it is not clear whether a such relationship (e.g. anxiety, depression, sleep-related dysfunctional beliefs etc.) co-exists in individuals with non-clinical sleep disturbance and various chronic health conditions. It is important to establish a possible relationship among patients with chronic health conditions and non-clinical sleep disturbance, and it is also of high importance to further use this understanding in order to improve people's lives by providing beneficial and effective treatments such as CBT. Whereas, to date, much of the research shows that CBT-I in the form of a self-help booklet is an effective and applicable treatment for patients with insomnia with or without chronic health conditions, it is unclear whether a CBT self-help booklet is also effective for patients with non-clinical sleep disturbance and chronic health conditions.

Hence, the current study is of particular importance and will contribute to the existing literature by taking a step forward, by evaluating the clinical effectiveness of multicomponent CBT for sleep problems in a unique participant sample of patients with chronic health conditions and non-clinical sleep disturbance.

Evidence derived from research involving patients with a chronic health condition and clinical insomnia suggests that a brief course of CBT-I may be a relevant and beneficial treatment for the management of non-clinical sleep disturbance in patients with chronic health conditions. Also, it was presumed that an easily accessible, brief, less complex and affordable CBT-I intervention would be considered beneficial to meet the needs for this group of patients. Hence, CBT-I in the form of self-help meets these requirements and may represent the most beneficial choice as an initial step treatment option for this type of population with sleep disturbance problems.

## **2.9. Aims and Hypotheses**

The aims of the current study are: 1) to explore whether individuals with non-clinical sleep disturbance at baseline have poor sleep quality, insomnia symptoms and as well high levels of psychological distress (anxiety, depression and stress), sleep-related dysfunctional beliefs and impaired health-related quality of life, and 2) to assess the effectiveness of CBT-I in the form of a published self-help booklet in a non-clinical sleep disturbance population with at least one chronic health condition. In particular, we aim to evaluate the potential ‘real world’ implementation of a brief CBT-I self-help booklet across a range of patients who self-reported sleep-related problems (or sleep disturbance) with chronic health conditions including various rheumatology diseases and irritable bowel syndrome to alleviate sleep disturbance. It is important to assess whether in fact this is the case.

Therefore, based on the aforementioned considerations, the following hypotheses are proposed:

**Hypothesis I:** Participants with non-clinical sleep disturbance at baseline will report poor sleep quality, high levels of insomnia severity, anxiety, stress and depression symptoms, sleep-related dysfunctional beliefs as well as impaired health related quality of life.

**Hypothesis II:** A brief CBT-based self-help booklet for sleep problems and insomnia will improve quality of sleep and reduce levels of insomnia severity in non-clinical disturbance patients with chronic health conditions who report either insomnia or mild sleep disturbance.

**Hypothesis III:** Participants with non-clinical sleep disturbance who experience significant improvements in sleep will exhibit a reduction in symptoms of anxiety, depression and stress and sleep-related dysfunctional beliefs and will improve health-related quality of life.

## **3. METHOD**

### **3.1. Introduction**

This chapter describes the methodological procedures that were undertaken to address the hypotheses of the current study.

Firstly, it outlines the approval procedures of the study, followed by a detailed description of the selection of participants, and recruitment approach process, the assessment measures, the intervention material and the statistical analyses that were implemented in the study.

### **3.2. Approvals**

#### **3.2.1. NHS Ethical and Management Approvals and Copyrighted Permissions**

Full ethical approval was granted by the NHS Lothian Local Research Ethics, South East Scotland Research Ethics Committee 1: Reference number: 12/SS/0114 (see Appendix 1). Also, NHS Management approval (see Appendix 2) was obtained from the NHS Lothian, Queen's Medical Research Institute, Edinburgh prior to the data collection. Copyrighted formal permissions for use of the measurements included in the study were obtained from the developers of the questionnaires. Permission was also obtained for the use of the CBT self-help booklet for the current study from the publisher of the booklet.

#### **3.2.2. Ethical Considerations**

Data collection for the study was conducted in accordance with the stipulations laid down by the NHS Research Ethics Committee (REC) and the Research and Development (R&D) in Scotland. Additionally, the British Psychological Society Code of ethics (BPS, 2009) and Health and Care Profession Council (HCPC) (2008)

were followed at all times in order to ensure that participants' rights were not breached and their safety was maintained.

For example, the standards of informed consent were addressed by providing a clear Participant Information Sheet and a Consent Form and by ensuring that all potential participants approached had ample time to discuss with others before making a decision on whether or not to participate in the study.

Confidentiality was addressed by attributing a unique code to each participant's data and by keeping any manual and electronic data in secure locations within the NHS (e.g. in a locked cabinet or on the NHS home drive) to comply with the Data Protection Act (1988).

### **3.3. Participants**

#### **3.3.1. Inclusion Criteria**

Potential participants (both male and female) were patients attending an appointment with their consultants. To be included in the study, participants were required to satisfy the following inclusion criteria:

- 1) To be diagnosed with a chronic health condition as defined by the Department of Health (2012) (see section 2.2.)
- 2) To be referred by their medical consultants
- 3) To be at least 18 years old
- 4) To have self-reported sleep disturbance
- 5) To speak sufficient English to be able to understand the printed material

### **3.4. Recruitment**

#### **3.4.1. Study Site**

Participants were recruited between April 2013 and March 2014 from two different outpatient clinics at Western General Hospital, Edinburgh, Scotland: (a) the Gastroenterology Tertiary Care outpatient clinic and (b) the Rheumatology outpatient clinic.

#### **3.4.2. Approach-Recruitment**

Potential participants were informed about the study by their medical consultants during their appointments. Those expressing an interest in the study were then referred by their consultants to the researcher, with whom they had the opportunity to discuss the research with the researcher prior to consenting to participate.

The researcher provided a brief oral description of the study's aims and procedures and answered direct questions. Those who self-reported sleep problems and who expressed an interest in participating in the study were given a package containing a detailed Participant Information Sheet (see Appendix 3), the Consent Form (see Appendix 4), the baseline questionnaires and a stamped addressed envelope for returning the signed Consent Form and completed questionnaires. Participants were advised to read the Participant Information Sheet carefully at home and told that they could omit answers to questions they did not wish to complete. Also, the researcher provided her contact details as well as the contact details of an independent advisor for those who required any further information or if any of the information on the Participant Information Sheet was not clear to them. Furthermore, the researcher asked for oral consent to telephone participants to remind them to return their completed questionnaires by post.



### **3.5. Procedure**

Upon receipt of the completed questionnaires and Consent Form, an intervention letter (i.e. to serve as a reminder of what the study was about and what procedures participants were being requested to follow (see Appendix 5) and the CBT self-help booklet entitled '*An Introduction to Coping with Insomnia and Sleep Problems*' (Espie, 2011) were sent by post to the participants. A more detailed description of the content of the self-help booklet is presented in the section 3.7.

Participants were requested to read the self-help booklet carefully and to practise the techniques described in the booklet for the following six weeks. Furthermore, they were requested to monitor how frequently they used the CBT self-help booklet during each of the six weeks by using a diary that was attached to the self-help booklet. Upon completion of the 6-week intervention, the same questionnaires accompanied by an intervention evaluation questionnaire were sent by post to the participants.

Participants were asked to complete these questionnaires and to return them to the researcher in the enclosed stamped addressed envelope the following week.

### **3.6. Measures**

#### **3.6.1. Demographic Characteristics Questionnaire**

At the commencement of the study, participants completed the demographic characteristics questionnaire, which was created by the researcher to obtain information on variables such as gender, age, educational level, marital status, ethnicity, work status and other important information (e.g. type and length of medical diagnosis, severity of their sleep problem, if they are currently receiving any psychological treatment for sleep problems, etc.) (see Appendix 6).

In addition, the following standardised questionnaires were administrated before and after the intervention:

### **3.6.2. Pittsburgh Sleep Quality Index (PSQI)**

The Pittsburgh Sleep Quality Index (Buysse et al., 1989; see Appendix 7) was used here since it is one of the recommended measures for assessing general sleep disturbance (Buysse et al., 2006). The PSQI questionnaire assesses general sleep disturbances over a 1-month time interval. The PSQI contains 19 self-rated questions generating seven component scores: (1) Duration of sleep, (2) Sleep disturbance, (3) Sleep latency, (4) Day dysfunction due to sleepiness, (5) Sleep efficiency, (6) Subjective sleep quality and (7) Use of Sleep medications.

The first four questions are open-ended, whereas questions 5 to 19 are rated on a 4-point Likert scale from 0 (no difficulty) to 3 (severe difficulty). The overall score is obtained by summing the seven subscales with a possible minimum score of 0 and a possible maximum score of 21. A total PSQI score higher than 5 is associated with poor sleep quality. There are no available cutoff scores for the component scales. The PSQI has good internal consistency with Cronbach's  $\alpha=0.83$  and reliability coefficient of  $r=.85$  (Buysse et al., 1989). Also, the PSQI has good internal consistency with Cronbach's  $\alpha=0.80$  in patients with various chronic health conditions with good or poor sleep quality (Carpenter & Andryskowski, 1998).

### **3.6.3. Insomnia Severity Index (ISI)**

The Insomnia Severity Index (Bastein, Vallieres & Morin, 2001; Morin, Belleville, Belanger & Ivers, 2011 see Appendix 8) is a recommended measure for measuring the perceived severity of insomnia symptoms (Buysse et al., 2006). The ISI contains the following categories: a) Severity of sleep-onset, sleep-maintenance and early morning awakenings, b) Degree of dissatisfaction with the current sleep pattern c) Noticeability of sleep problems by others, d) Level of distress or worry caused by the current sleep problems, and e) Degree to which sleep problems interfere with daily functioning. The items are answered on a 5-point Likert scale ranging from 0 (no problem) to 4 (very severe problem). The total score is obtained by adding the seven items ranging from 0 to 28 and is interpreted as follows: 0-7, no clinically significant

insomnia; 8-14, sub-threshold insomnia; 15-21, clinical insomnia of moderate severity; 22-28, severe clinical insomnia. The ISI has good overall internal consistency for both community and clinical samples with Cronbach's  $\alpha = 0.90$  and  $0.91$  respectively.

#### **3.6.4. Dysfunctional Beliefs and Attitudes about Sleep Scale-16 Item Version (DBAS-16)**

The DBAS-16 (Morin, Valliers & Ivers, 2007; see Appendix 9) is an abbreviated and the latest version of the original DBAS-30 (Morin, 1994) and the most commonly used questionnaire (Carney et al., 2010) in assessing the existence and level of dysfunctional beliefs concerning sleep. Items are rated using a Likert-type scale from 0 (strongly disagree) to 10 (strongly agree). The total score is calculated using the average score of all 16 items with a higher score indicating a higher level of dysfunctional beliefs and attitudes about sleep.

The psychometric properties of DBAS-16 are adequate (Morin et al., 2007). In clinical samples the internal consistency was reported as  $\alpha = .77$  and test-retest reliability coefficient of  $r = .83$  (Morin et al., 2007).

#### **3.6.5. Depression Anxiety and Stress Scale-21 (DASS-21)**

The DASS-21 (Lovibond & Lovibond 1995; see Appendix 10) was selected for use in the current study since it assesses the three negative emotional states: a) depression, b) anxiety and c) stress that are related to sleep. Items are rated using a 4-point Likert scale from 0 (did not apply to me at all) to 3 (applied to me very much, or most of the time). It consists of a set of three self-report scales designed to assess anxiety, depression and stress respectively. Each scale contains seven items and the total score for each scale is obtained by summing the responses for the relevant items and multiplying them by 2. The Cronbach's  $\alpha$  for the depression,

anxiety and stress scales are 0.88; 0.82 and 0.90 respectively in a non-clinical population (Henry & Crawford, 2005).

In addition, the DASS-21 is a valid and reliable measure in both clinical and non-clinical samples (Antony, Bieling, Cox, Erns & Swinson, 1998). The DASS-21 can be used both for research purposes and as a routine clinical outcome measure (Lovibond & Lovibond, 1995).

### **3.6.6. Health-Related Quality of Life (SF-36v2)**

The SF-36v2 (Ware et al., 2008; see Appendix 11) is recommended for measuring HRQoL within the context of insomnia (Buysse et al., 2006) and for the current study the standard 4-week recall was used since it is more appropriate in cases where the questionnaire is administered once or after a period of four weeks (Ware et al., 2008). The SF-36v2 is a 36-item questionnaire yielding a profile of health status across eight health domains: Physical Functioning (PF), Role Physical (RP), Bodily Pain (BP), General Health (GH), Vitality (VT), Social Functioning (SF), Role Participation with Emotional Health Problems (Role Emotional) (RE), and Mental Health (MH). The SF36v2 items are rated using a Likert scale. For example, 25 items are rated on a 5-point scale; 10 items are rated on a 3-point scale and one item is rated on a 6-point scale. A computer-based software package 4.5™ was used to score the SF-36v2 under licence from Quality Metric Incorporated. The eight health domains are computed and two summary scores are derived: a) a physical component summary (PCS) and b) a mental component summary (MCS). The PF, RP, BP and GH are more strongly correlated with the PCS factor, which contributes more towards the PCS score. On the other hand, the VT, SF, RE and MH are more strongly correlated to the MCS factor which contributes more to the MCS score. The scores are translated from 0 (lowest score) to 100 (highest score). Higher PCS and MCS scores indicate a better health-related quality of life. Cronbach's  $\alpha$  is not calculated for PCS and MCS because these summary measures are linear combinations of the eight scales. The reliability coefficient for the PCS and MCS are .96 and .93 respectively (Maruish, 1993).

### 3.7. The CBT Intervention

The self-help booklet: *'An Introduction to Coping with Insomnia and Sleep Problems'* (Espie, 2011, see Appendix 12) comprises two parts.

The first part of the booklet, entitled *'About Insomnia'*, aims to help patients to understand in detail what insomnia is, to help them identify other sleep disorders, and to understand the relationship between poor sleep and low mood. It explains what causes insomnia (e.g. predisposing, precipitating and perpetuating factors) and what the different treatments for insomnia are, e.g. medication, psychological therapies (CBT) and other therapies, e.g. herbal remedies.

The second part of the booklet, entitled *'Coping with Insomnia'*, provides a preliminary introduction to the self-management approach to insomnia (such as setting personal goals, maintaining a sleep diary, and the calculation of sleep efficiency), followed by different strategies that patients can use to improve their sleep. These include improving sleep hygiene (e.g. explaining what sleep hygiene is, the lifestyle and bedroom factors associated with good sleep hygiene), improving preparation for sleep (e.g. bedtime wind-down, learning to relax), improving the bed-sleep connection (e.g. the bed is for sleep rule, the quarter of an hour rule), making your sleep pattern the best it can be, dealing with a racing mind (dealing with negative thoughts), evaluating how you feel during the day, and trying to make lasting improvements to sleep.

Lastly, the CBT-I SH booklet also includes other sources of information that might help (e.g. websites and other books pertaining to self-management of sleep problems) (see Table 1.1).

Table 1.1

*Content of the CBT-I Self-Help Booklet*

Booklet titles and subheadings	Summary of contents
<b>Part 1: About insomnia</b>	
What is insomnia?	Understand what insomnia means; it helps to
What causes insomnia?	identify other disorders of sleep; sleep and mood
Different treatments for insomnia	relationship; prevalence of insomnia; factors causing insomnia (predisposing, precipitating and perpetuating factors); different treatments of insomnia (e.g. medications, herbal remedies and CBT)
<b>Part 2: Coping with Insomnia</b>	
Setting clear goals	Self-management: personal goals; keeping sleep diary; calculating sleep efficiency
Improving sleep hygiene	Explain what Sleep Hygiene is
Improving your preparation for sleep	Learning to relax: Physical and Mental relaxation
Improving your bed-sleep connection	Stimulus control
Making your sleep pattern the best it can be	Setting and Adjusting your sleep window; Sleep Restriction
Dealing with a racing mind	Cognitive therapy: thought diary; setting realistic expectations about sleep
Evaluating how you feel during the day	Use the thought evaluator to deal with your daytime thinking
Making lasting improvements to your sleep	Encouraging and advising to continue with all the CBT techniques
Other things that might help	Other sources of information: e.g. more detailed self-help books and different websites

### **3.7.1. Diary**

Attached to the self-help booklet is a diary entitled '*Frequency of use of the CBT self-help guide*'. Participants were asked to indicate whether they used the CBT self-help booklet daily, 3-5 times, 1-2 times, or not at all. They were also asked to estimate the total use each week in hours and minutes (see Appendix 13).

### **3.7.2. Participant Evaluation: Treatment Satisfaction**

Following completion of the intervention, participants also completed a brief evaluation questionnaire comprising nine close-ended questions requiring them to respond by using a 5-point Likert scale and three open-ended questions to enable the researcher to evaluate participants' perceptions of the self-help booklet with regard to alleviating their sleep problems (e.g. expectations, satisfaction or difficulties in the use of the self-help booklet) (see Appendix 14).

## **3.8. Study Design**

A within subject/repeated-measures design was implemented to evaluate the effectiveness of the intervention. Within subject design is a design in which the same group of participants participates in all conditions (Shuttleworth, 2009). For the current study, two time points were used: a) before the intervention and b) after the intervention. The advantages of a within subject design are: a) it requires fewer participants and resources and b) it reduces the effects of natural variation among participants upon the results (Shuttleworth, 2009).

### **3.9. Data Analyses**

A series of t-tests/paired-samples t-tests were conducted for all outcome measures to compare the pre-treatment and post-treatment mean scores of the two related groups to detect whether there are any statistically significant differences between these means.

### **3.10. Sample size**

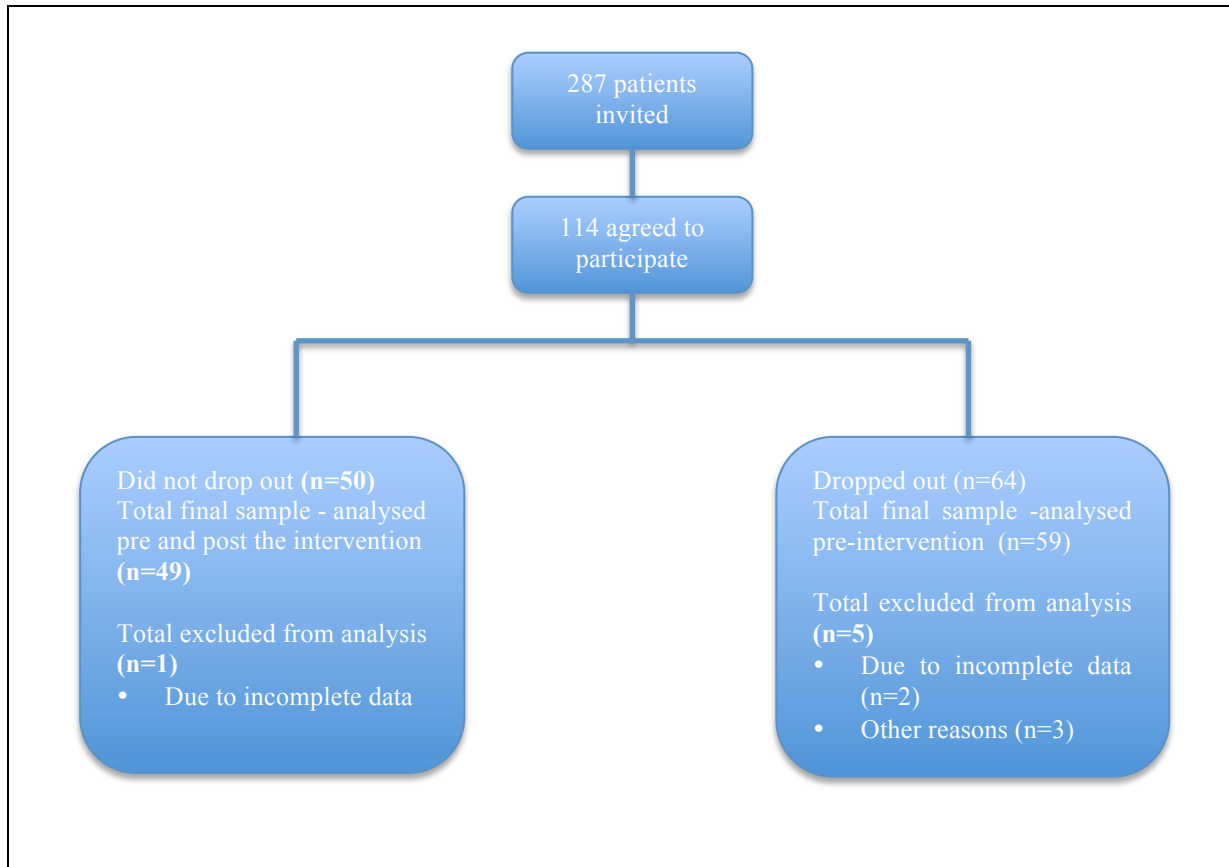
#### **3.10.1. Power calculation and sample size**

An *a priori* sample calculation was conducted using the G\* power program (Faul, Erdfelder, Lang, & Buchner, 2007; Faul, Erdfelder, Buchner & 2009) to determine how many participants were needed for a repeated measures design. To detect an effect size of 0.3 (small effect) with a statistical power of 0.8 (80%), the G\*power program suggested at least 90 participants. It was anticipated that one would recruit approximately 120 participants in order to allow for a 25% dropout rate. The QMU statistician also confirmed the sample calculation size. However, the estimated sample was not achieved and the reasons related to this are described below.

A flow diagram (Figure 1.1) is presented on the following page, which shows the recruitment, participation and completion phases of all study components. Of 287 participants who expressed an interest in the study, 114 participants completed baseline questionnaires and received the intervention. In total, 50 participants successfully completed all the study components. However, one participant was later excluded from the final analyses due to incomplete assessments resulting in an overall sample size of 49 participants.

The remaining 64 participants withdrew from the trial for the following reasons: illness flare-ups, surgery, hospitalisation, workload demands, family stressors, or being away on holiday. In addition, a further five participants were excluded due to incomplete data and/or other reasons (e.g. they requested to be excluded from the study).





*Figure 1.1* Flow diagram of recruitment, participation and completion of all study components.

## 4. Results

### 4.1. Data Screening

Data were analysed using the statistical software for the Social Sciences, SPSS for Windows (Version 21.0, Armonk, NY: IBM Corp.). Prior to analyses, data were screened for missing values. In cases where no more than two items/answers were missing in a multi-item scale (e.g. a 16-item scale) and where no more than one item/answer was missing in a 7-item scale, the missing values were adjusted.

For the adjustment, the formula  $Y = (z \times N) / M$  was used, where  $z$  was the score for questions answered  $M$  was the maximum score for the number of questions answered  $N$  was the maximum score for all questions,  $Y$  was the score as if all questions had been answered (this procedure was adopted following personal communication with Dr. Robert Rush, QMU, statistician). This procedure resulted in an overall variation across the total number of cases. For example, in some cases, analyses were based on data for 47 or 48 participants (see Table 1.2). However, this procedure was not applied for the PSQI due to the scoring instructions of the questionnaire.

An assessment of the normality of all continuous outcomes was performed using the Shapiro-Wilk test. The distribution of all included variables across the two time points (pre-and post-intervention) was assessed for normality. Parametric tests were used for cases that were normally distributed, whereas in cases where the data were not normally distributed, non-parametric tests were used.

### 4.2. Participants' demographic characteristics

As stated previously in section 3.9.1. a total of 49 participants completed the intervention. The majority of the participants were female (89.8%;  $n=44$ ) of Scottish ethnic origin (81.6%;  $n=40$ ) and the mean age of the participants was 56.20 years (range= 22 to 80 years;  $SD=14.3$ ). Age was normally distributed. Thirty-three participants (67.3%) were married/cohabiting, whereas the remaining 16 (32.7%) reported being single, widowed or separate/divorced.

With regard to educational level, 19 participants (40.4%) reported having a higher educational level (college or university); 46.8% ( $n=22$ ) had secondary school education (e.g. standard grades, SVQ/NVQ, Highers or Advanced Highers) and 12.8% ( $n=6$ ) indicated that they did not have any educational qualifications. Furthermore, 19 participants (39.6%) were retired; 12 (25.0%) were employed in a part-time position and four (8.3%) were employed in a full-time capacity. The remaining 12 (25%) participants were unemployed for reasons related to their chronic health condition and one participant (2.1%) was unemployed for reasons unrelated to their chronic health condition. Of those who reported working, seven participants (87.5%) indicated they were not night shift workers, while one participant (12.5%) reported that he was a night shift worker.

Of the 49 participants, 10 (20.4%) had diagnosis of IBS and 39 (79.6%) had diagnosis of different rheumatoid diseases (such as rheumatoid arthritis, lupus). All participants self-reported that they had sleep problems and that they had experienced such problems from 2 months to over 40 years.

With regard to sleep medications, 40 (83.3%) participants indicated that they were not taking any sleep medications and that they did not have any sleep problems prior to the onset of their chronic health condition.

With regard to sleep-related problems, 26 participants (53.1%) reported that their sleep problems had started at the same time as the onset of their chronic health condition. Furthermore, 40 participants (83.3%) indicated that when the symptoms of their health condition flare-up, their sleep gets worse. More than half of the participants (63.8%) reported that when their chronic health condition goes through periods of improvement, their sleep also gets better.

Participants reported that they did not receive any psychological treatment for sleep problems, though one participant reported that he had been using tapes to help him relax. Finally, 46 (93.9%) participants reported that they had excellent to good reading and comprehension abilities.

### **4.3. Descriptive Statistics of Participants' Outcomes Measures at Baseline**

With regard to the first hypothesis, it was predicted that individuals with non-clinical sleep disturbance at baseline would have poor sleep quality and severe insomnia symptoms, as well as high levels of psychological distress (anxiety, stress and depression), sleep-related dysfunctional beliefs and poor health-related quality of life.

Descriptive statistics (e.g. means and standard deviations) of participants for all survey measures at baseline are presented in Table. 1.2 on page 61.

With regard to sleep quality as measured by PSQI (Buysse et al, 1989), 46 participants (92.1%) reported poor sleep quality, while the remaining three participants (7.9%) reported good sleep quality.

With regard to insomnia severity as measured by the ISI (Bastein et al, 2001; Morin et al., 2011), the mean score of 48 participants was 16.96, which is in the clinical moderate insomnia severity range. Specifically, the current sample included, one participant (2.1%) with non-clinical insomnia, 15 participants (31.3%) with sub-threshold insomnia, 22 participants (45.8%) with clinical moderate insomnia and 10 participants (20.8%) with clinical severe insomnia (Bastein et al, 2001; Morin et al., 2011). In sum, 47 participants reported either sub-threshold or clinically significant insomnia.

With regard to the anxiety, depression and stress subscales (DASS-21; Lovibond, & Lovibond, 1995), the participants were classified with moderate anxiety, depression and stress with mean scores of 12.12 ( $n=48$ ); 15.95 ( $n=48$ ) and 19.85 ( $n=49$ ) respectively (Lovibond & Lovibond 1995). In particular, for the anxiety subscale, 20 participants (41.7%) were classified within normal range, one participant (2.1%) was classified with mild anxiety, 13 participants (27.1%) with moderate anxiety, three participants (6.3%) with severe anxiety and 11 participants (22.9%) were classified with extremely severe anxiety. With respect to the depression subscale, participants were classified as follows: 17 participants (35.4%) were classified within the normal range, nine participants indicated (18.8%) mild depression, seven participants (14.6%) indicated moderate depression, four participants (8.3%) indicated severe

depression and 11 participants indicated (22.9%) extremely severe depression. Finally, regarding the stress scale, 17 participants (34.7%) were within normal range, eight participants (16.3%) reported mild stress, nine participants (18.4%) reported moderate stress, seven participants (14.3%) reported severe stress and eight participants (16.3%) reported extremely severe stress.

The dysfunctional sleep-related beliefs (DBAS-16; Morin et al., 2007) and the health-related quality of life measurements (HRQoL SF: 36; Ware et al., 2008) have no published cut-off score. Therefore, the minimum and maximum scores were used for these measurements to indicate the severity of the problem. The minimum and maximum scores for the DBAS-16 ranged from 0 to 10 respectively; a higher score indicates higher levels of sleep-related dysfunctional beliefs. Participants reported means scores of 4.85, which suggest moderate levels of sleep-related dysfunctional beliefs.

The scoring of the HRQoL for both physical and mental components indicates from 0 (poorest quality of life) to 100 (best possible quality of life). The mean HRQoL in our sample was 34.7 and 41.3 for the physical and mental components respectively. Participants' HRQoL (for both mental and physical components) was below 50, which suggested that they had significantly impaired HRQoL.

In summary, the current results suggest that, of the individuals who had non-clinical sleep disturbance, the majority reported poor sleep quality, clinically moderate levels of insomnia severity and moderate to extremely severe levels of psychological symptoms (anxiety depression and stress), moderate sleep-related dysfunctional beliefs and impaired HRQoL. Collectively, these findings suggest that the current population with non-clinical sleep disturbance could benefit from a brief CBT-intervention in the form of a self-help booklet. The results of the effectiveness of the CBT intervention are presented on section 4.4.

Table 1.2

*Descriptive statistics of participants for survey measures at baseline*

<b>Measure</b>	<b>N</b>	<b>M</b>	<b>SD</b>
PSQI	38	11.8	3.82
ISI	48	17	4.94
DBAS-16	47	4.84	1.94
DASS 21:Anxiety	48	12.1	10.7
DASS-21: Depression	48	16	13
DASS-21: Stress	49	19.9	10.8
SF-36: PCS	48	34.7	9.86
SF-36: MCS	48	41.3	12.6

*Note. PSQI=Pittsburgh Sleep Quality Index; ISI=Insomnia Severity Index; DBAS-16=Dysfunctional beliefs and attitudes about sleep; SF-36-PCS=Physical component; SF-36-MCS=Mental component*

#### **4.4. Statistical Analyses**

##### **4.4.1. Effects of the Intervention**

With regard to the second hypothesis, it was hypothesised that a brief CBT-based self-help booklet for sleep problems and insomnia would improve quality of sleep and reduce levels of insomnia severity in non-clinical disturbance patients with chronic health conditions who report either insomnia or mild sleep disturbance. With regard to the third hypothesis, it was hypothesised that participants with non-clinical sleep disturbance who experience significant improvements in sleep will exhibit a reduction in symptoms of anxiety, depression and stress and sleep-related dysfunctional beliefs and will improve their HRQoL. Therefore, in order to examine the effectiveness of the intervention on these outcomes, a series of paired sample t-tests and Wilcoxon signed-rank tests were conducted to compare each of the outcomes before and after the intervention. The results are presented below.

#### **4.4.2. Sleep Quality**

There was a significant difference between the pre-intervention total scores ( $M=11.7$ ,  $SD=3.93$ ) and the post-intervention total scores for sleep quality ( $M=9.26$ ,  $SD=4.64$ ),  $t(34) = 4.10$ ,  $p < .001$  in 35 participants. Post-intervention scores were significantly lower, indicating better sleep quality. These results suggest that the intervention was effective in significantly improving sleep quality.

Also, further analyses were conducted to identify which sleep quality components significantly contributed to overall improved sleep quality. Each sleep quality component score (e.g. duration of sleep, sleep disturbance, sleep latency, day dysfunction due to sleepiness, sleep efficiency, overall sleep quality, and need of medication to sleep) was compared before and after the intervention. The results indicated a significant decrease in the sleep disturbance component scores and improvements in overall sleep quality at post-treatment assessment ( $p < .001$ ). Also, there was a significant increase in total sleep time per night ( $p = .034$ ) and both sleep quality components of sleep latency ( $p = .042$ ) and day dysfunction due to sleepiness ( $p = .031$ ) showed significant differences before and after the intervention.

However, sleep quality components scores with regard to the need for sleep medications ( $p = .552$ ) and sleep efficiency ( $p = .083$ ) showed no significant differences before and after the intervention.

#### **4.4.3. Insomnia Severity Index**

There was a significant difference between the pre-intervention total scores ( $M=17.1$ ,  $SD=4.90$ ) and post-intervention total scores for insomnia severity ( $M=13.7$ ,  $SD=6.58$ ),  $t(46)=4.41$ ,  $p < .001$  in 47 participants. Post-intervention insomnia severity scores were significantly lower. These results suggest that the intervention was effective in reducing insomnia severity.

#### **4.4.4. Dysfunctional Beliefs and Attitudes about Sleep**

There was a significant difference between the pre-intervention total scores ( $M=4.92$ ,  $SD=1.89$ ) and post-intervention total scores for dysfunctional sleep-related beliefs ( $M=4.39$ ,  $SD=2.05$ ),  $t(45)=2.38$ ,  $p=.022$  in 46 participants. Post-intervention dysfunctional sleep-related beliefs scores were significantly lower. The results suggest that the intervention significantly reduced sleep related dysfunctional beliefs.

#### **4.4.5. Stress**

There was a significant difference between the pre-intervention total scores and post-intervention total scores for stress  $z=-2.653$ ,  $p=.008$  in 49 participants. The results suggest significantly lower levels of stress.

#### **4.4.6. Anxiety**

There was no significant difference between the pre-intervention total scores and post-intervention total scores for anxiety,  $z=-1.409$ ,  $p=.159$  in 48 participants.

#### **4.4.7. Depression**

There was no significant difference between the pre-intervention total scores and post-intervention total scores for depression,  $z=-1.812$ ,  $p=.070$  in 48 participants.



#### **4.4.8. Health-Related Quality of Life (HRQoL)**

##### **4.4.8.1. HRQoL: Physical Health Component**

There was no significant difference between the pre-intervention total scores ( $M=34.7$ ,  $SD=9.86$ ) and post-intervention total scores for physical component ( $M=35.9$ ,  $SD=9.73$ ),  $t(47) = -1.56$ ,  $p = .125$  in 48 participants.

##### **4.4.8.2. HRQoL: Mental Health Component**

Similarly, the results indicated that there were no significant difference between the pre-intervention total scores ( $M=41.3$ ,  $SD=12.6$ ) and post-intervention total scores for mental component ( $M=41.9$ ,  $SD=12.4$ ),  $t(47) = -.507$ ,  $p = .614$  in 48 participants.

In sum, participants who completed a brief CBT self-help booklet intervention for sleep showed an improvement in overall sleep quality and reductions in symptoms of sleep-related dysfunctional beliefs, insomnia severity and stress following the intervention. However, no significant improvements were found in HRQoL (for both physical and mental components). In addition, there were no significant reductions in symptoms of anxiety and depression following completion of the intervention.

Table 1.3

*Pre and Post Treatment Measures for CBT*

<b>Outcomes</b>	<b>Pretest</b>		<b>Posttest</b>		<b>t</b>	<b>r</b>
	<b>M</b>	<b>SD</b>	<b>M</b>	<b>SD</b>		
Sleep Quality (PSQI)	11.7	3.93	9.26	4.64	4.107*	.57
Insomnia Severity (ISI)	17.1	4.90	13.7	6.58	4.418*	.54
Beliefs and Attitudes about Sleep (DBAS-16)	4.92	1.89	4.39	2.05	2.380*	.33
PC-HRQoL (SF-36 Physical Health Component)	34.7	9.86	35.9	9.73	-1.561	.22
MC-HRQoL (SF-36 Mental Health Component)	41.3	12.6	41.9	12.4	-.507	.07

*Note:* M=Mean; SD=Standard Deviation; T score for paired t-test; r=Effect size  
p<.05

Table 1.4

*Pre and Post Treatment Measures for CBT*

<b>Outcomes</b>	<b>Pretest</b>	<b>Posttest</b>	<b>z</b>	<b>r</b>
	<b>Mean Ranks</b>	<b>Mean ranks</b>		
Stress	20.25	24.24	-2.653*	-.38
Anxiety	17.65	18.20	-1.409	-.20
Depression	18.09	23.82	-1.812	-.26

*Note:* Z score for Wilcoxon t-test

\*p < .05

## **4.5. Further Explanatory Statistical Analysis**

Further explanatory analyses were performed to determine whether a particular group of participants in the sample benefited from the intervention. Since the current intervention was self-administrated CBT without any professional support, it required a good level of literacy and education in order to understand the written material and to use and practice the techniques described in the CBT self-help booklet to improve sleep.

Therefore, post-treatment total scores were subtracted from the pre-treatment total scores of sleep quality (PSQI). Based on this equation, a new variable was created (PSQI-change scores). Subsequently, an independent sample t-test was performed to examine whether there are any significant differences between PSQI changed scores and education levels (e.g. higher education and secondary education).

### **4.5.1. Sleep Quality Changed Scores and Education Levels**

Participants with a higher educational level had improved sleep quality ( $M=-3.80$ ,  $SD=3.41$ ) compared to those with a lower (secondary) educational level ( $M=-.933$ ,  $SD=3.39$ ),  $t(28)=-2.310$ ,  $p=.028$ .

## **4.6. Intervention Evaluation and Frequency of use of the CBT Self-Help booklet**

### **4.6.1. Participant Evaluation: Treatment Satisfaction**

Overall, approximately 50% of participants rated the intervention good and 41.3% stated that they would probably recommend the use of the CBT-I self-help booklet to other people with sleep problems. A detailed summary of participant acceptability and satisfaction with the treatment as well as the estimated total usage of the CBT self-help booklet for each week is presented in the Appendices (see Appendix 15 & 16 respectively).

## **4.7. Assessment of Attrition**

### **4.7.1. Comparison of demographic profiles of participants who did and who did not dropout**

The demographic profiles of participants who did and did not dropout are presented in Table 1.5.

Further analyses were performed using the demographic profiles and baseline scores of participants who did and did not drop out in order to determine if there were any differences with regard to the demographic profiles and baseline scores between the two groups. Prior to any analysis, normality tests were performed for the continuous variables (e.g. age) for both groups. Age was normally distributed.

Consequently, an independent sample t-test was performed to examine if there were any significant differences with regard to age between the two groups.

The results suggested that there were no significant differences between these two groups in relation to age (see Table 1.5).

Concerning the categorical variables (gender, education, type of chronic health condition and marital status), Pearson chi-square tests were performed to examine if there were any differences between the two groups.

The results suggested that there were no differences between the two groups with regard to gender, education, type of condition and marital status (see Table 1.5). This indicates that demographic characteristics were not related to the dropout rate.

Table 1.5

*Demographic profiles: Comparison of participants who did and did not dropout*

Variable(s)	Dropped out	Did not dropout	p
Continuous			
Age (Years)	53.39±15.01(59)	56.20±14.27(49)	.324
Mean ± SD			
Categorical	N (%)	N (%)	p
Gender			
Male	14 (23.7%)	5 (10.2%)	.066
Female	45 (76.3%)	44 (89.8%)	
Education level			
Higher education	16 (28.1%)	19 (40.4%)	.398
Secondary education	31 (54.4%)	22 (46.8%)	
No education	10 (17.5%)	6 (12.8%)	
Type of condition			
IBS	21 (35.6%)	10 (20.4%)	.082
Rheumatoid diseases	38 (64.6%)	39 (79.6%)	
Marital status			
Married/cohabiting	36 (62.1%)	33 (67.3%)	.570
Single/widowed/separate	22 (37.9%)	16 (32.7%)	
/divorced			

#### 4.7.2. Comparison of Baseline Psychological Profiles of Participants who did drop out and those who did not dropout of the study

Data were assessed for normality using the Kolmogorov-Shapiro and the Shapiro-Wilk test. Pre-treatment assessment total scores (Sleep quality, Insomnia Severity Index, dysfunctional beliefs and attitudes about sleep, anxiety, stress, depression and health-related quality of life) were compared for the two groups to determine whether any of the variables differentiated these two groups. The results suggested that the two groups did not differ across any of the study variables (see Table 1.6 & Table 1.7). This indicates that the results are not biased and were not related to the dropout rate.

Table 1.6

*Comparison of baseline psychological profiles of participants who did and did not dropout.*

Baseline Variables	Dropped out			Did not Dropout			t	p
	(N)	M	SD	(N)	M	SD		
PSQI	50	12.8	3.39	38	11.8	3.82	-.1.215	.228
ISI	58	17.5	5.40	48	17	4.94	-.548	.585
DBAS	58	5.27	1.88	47	4.84	1.94	-1.143	.256
Stress	57	19.5	11.8	49	19.9	10.8	.174	.862
SF-36: PCS	58	33.3	11.2	48	34.7	9.86	.674	.500
SF-36: MCS	58	41.6	12.4	48	41.3	12.6	-.159	.874

*Note. Independent t-test*

PSQI=Pittsburgh Sleep Quality Index; ISI=Insomnia Severity Index; DBAS-16=Dysfunctional beliefs and attitudes about sleep; SF-36: PCS=Physical component; SF-36:MCS=Mental component

Table 1.7

*Comparison of baseline psychological profiles of participants who did and did not dropout*

<b>Baseline</b>	<b>Dropped out</b>		<b>Did not Drop Out</b>			
Variables	(N)	Mean Ranks	(N)	Mean Ranks	U	p
Anxiety	58	56.3	48	50.0	1226	.292
Depression	57	53.2	48	52.7	1355	.933

*Note.* Mann-Whitney t-test

In sum, the current results show that non-clinical sleep disturbance patients with chronic health conditions had poor sleep quality, clinically moderate levels of insomnia severity and moderate levels of psychological distress (e.g. anxiety, depression and stress) and moderate levels of sleep-related dysfunctional beliefs as well as impaired HRQoL. With regard, to the effects of the intervention, the results suggest that a brief CBT-SH booklet can significantly improve sleep patterns and reduce both sleep-related dysfunctional beliefs and stress symptoms among patients with non-clinical sleep disturbance and chronic health conditions. However, this group of patients did not show reductions in symptoms of anxiety and depression and improved HRQoL.

## 5. DISCUSSION

The main aims of this study were to assess: 1) whether individuals with non-clinical sleep disturbance at baseline had poor sleep quality, severe symptoms of insomnia, high levels of psychological distress (anxiety, depression and stress) and sleep-related dysfunctional beliefs as well as poor health-related quality of life, and 2) whether a brief CBT-I self-help booklet was effective in a non-clinical sleep disturbance population with at least one chronic health condition, recruited from two Rheumatology and Gastroenterology hospital outpatient clinics. Considering individuals who self-report sleep disturbance is of particular importance since any sleep complaint may be perceived as problematic.

To achieve the aims of the current study, three main hypotheses were addressed. Firstly, that individuals with non-clinical sleep disturbance at baseline will demonstrate high levels poor sleep quality, high severe insomnia symptoms, high levels of psychological distress (anxiety, depression and stress), sleep-related dysfunctional beliefs and poor health-related quality of life.

Secondly, that a brief CBT based self-help booklet for sleep problems and insomnia will improve quality of sleep and reduce levels of insomnia severity in non-clinical disturbance patients with chronic health conditions who report either insomnia or mild sleep disturbance.

Thirdly, that participants with non-clinical sleep disturbance who experience significant improvements in sleep will experience a reduction in symptoms of anxiety, depression and stress and sleep-related dysfunctional beliefs, and improved health-related quality of life. The findings for each hypothesis are discussed below.

With respect to the first hypothesis, the results supported that the non-clinical sleep disturbance population had poor sleep quality, insomnia symptoms and moderate symptoms of psychological distress (anxiety, depression and stress) and impaired health-related quality of life, suggesting that a brief CBT-I self-help booklet would be beneficial for this type of population. Consequently, in relation to the second aim of the effectiveness of the intervention and with regard to the second hypothesis, the results of the current study indicated that the provision of a brief, multicomponent



CBT-I SH booklet significantly helped participants to alleviate their sleep problems. In particular, the CBT-I SH booklet can significantly improve chronic health patients' overall sleep quality and reduced insomnia severity symptoms (as measured by self-report questionnaires PSQI and ISI respectively). The explanatory analyses, which aimed to further assess which PSQI component contributed to overall sleep quality, revealed a significant reduction in perceived sleep disturbance and overall sleep quality, followed by better perceptions of total sleep time, sleep latency and day dysfunction due to sleepiness. However, sleep medication and sleep efficiency components did not show any significant difference towards improved overall sleep quality following the completion of the intervention.

With respect to the third hypothesis, participants reported reduced levels of sleep-related dysfunctional beliefs and a reduction of stress following the intervention. However, they did not show any significant reduction to their symptoms of anxiety and depression. In addition, participants did not show improved health-related quality of life following the intervention.

To our knowledge, this is the first study examining the effectiveness of a CBT-I SH booklet with virtually no clinical support for non-clinical sleep with chronic health conditions. In sum, the current results showed that, despite the fact that the current sample was a non-clinical sleep disturbance population with chronic health conditions, these individuals showed poor sleep quality and moderate insomnia severity symptoms. Furthermore, the current sample was shown to have moderate psychological symptoms (e.g. anxiety, depression and stress) that differ from normal profiles. Accordingly, the results suggest that a brief CBT-I SH booklet without professional support may be effective in alleviating sleep problems, reducing sleep-related dysfunctional beliefs and stress levels among patients with chronic health conditions. However, no significant results were found for anxiety and depression symptoms and health-related quality of life. The results of the effectiveness of the CBT self-help booklet are discussed in more detail below and further considered in relation to studies in the field.

The findings of this study support previous studies that evaluated the effectiveness of similar multicomponent CBT-I (targeting both cognitions and behaviours) self-help

interventions for patients with comorbid insomnia (e.g. Morgan et al., 2012; Rybarczyk et al., 2011; Jermelov et al., 2012; Casault et al., 2015; Rybarczyk et al., 2005) and among a healthy population with insomnia (e.g. Mimeault & Morin, 1999; Morin et al., 2005) with CBT-I self-help improving sleep. However, in making these comparisons, it is necessary to take into account the methodological or procedural differences between the studies. For example, previous studies in the related field have performed pre-intervention participation screening using different tools (e.g. clinical diagnostic criteria, and/or questionnaires) to determine insomnia, and they differ in sample composition (e.g. type of chronic health conditions, age) and type of measurements in sleep outcomes and secondary outcomes. In addition, the effectiveness of CBT-I self-help interventions varied in terms of the degree of therapist support. These methodological or procedural differences between the studies are critical since different methods, data and findings may lead to different conclusions.

Previous studies have supported the effectiveness of CBT-I SH combined with minimal support (e.g. Mimeault & Morin, 1999; Jermelov et al., 2012; Casault et al., 2015; Rybarczyk et al., 2011; Rybarczyk et al., 2005) or optional access to telephone support (e.g. Morgan et al., 2012; Morin et al., 2005) in patients with insomnia. For example, Mimeault and Morin (1999) found that telephone support can enhance the effects of the CBT-I self-help booklet in patients with primary insomnia but this extra effect disappeared at the 3-month follow-up. In contrast, another study found that CBT-I self-help, along with brief therapist telephone contact, improved the treatment effect in patients with comorbid insomnia (e.g. Jermelov et al., 2012). Another study found that a CBT-I self-help booklet with optional telephone support was effective among older patients (mean age 67 years) with various chronic health conditions and chronic insomnia (e.g. Morgan et al., 2012). The results also showed a low use of telephone support during the intervention and no differences were found post-treatment between telephone support users and non-users. These results showed that telephone support might not improve treatment effects, although the authors stated that, without telephone support, participants might have less improvement (Morgan et al., 2012).

In sum, these studies highlight the potential effectiveness of CBT in the form of self-help with minimal therapist support in patients with comorbid insomnia. Whereas, the current real world-based study goes a step further by indicating that CBT-I SH booklet also has the potential to be effective in clinical settings without the provision of professional support for patients with chronic health conditions and non-clinical sleep disturbance.

In addition, the current study did not indicate that improved sleep is associated with a reduction in symptoms of anxiety and depression. These findings are not consistent with previous CBT-I SH booklet studies within the context of a clinical population in patients with cancer (e.g. Casault et al., 2015) and in patients with primary insomnia (e.g. Mimeault & Morin, 1999; van Straten et al., 2009; Morin et al., 2005) which found that CBT-I SH leads to a reduction in symptoms of anxiety and depression. Similarly, studies administering group CBT-I to patients with cancer found that group CBT-I can reduce depressive symptoms (e.g. Quesnel et al., 2003; Savard et al., 2005) and anxiety symptoms (e.g. Savard et al., 2005). On the other hand, other CBT-I group studies did not show a significant reduction in anxiety symptoms in patients with cancer (e.g. Quesnel et al., 2003) or in patients with various chronic health conditions (e.g. Rybarczyk et al., 2002), nor a reduction in depression symptoms in patients with chronic pain (e.g. Currie et al., 2000).

In general, there is some discrepancy in relation to the impact of CBT-I in reducing anxiety and depression symptoms among patients with insomnia or comorbid insomnia. Alternative explanations of there being no significant results in relation to anxiety and depression symptoms in this type of group of patients may be that anxiety and depression are more related to patients' health conditions and not to sleep *per se*, since anxiety and depression are common symptoms among patients with chronic health conditions. Moreover, a brief CBT-I self-help booklet may not have a significant effect on participants who experience less severe (moderate) levels of anxiety and depression or moderate levels of depression and anxiety may not be a problem. Additionally, depression and anxiety may be more likely in individuals with greater disease severity or an uncertain prognosis (e.g. cancer).

Finally, another possible explanation may be the use of a different tool in assessing anxiety and depression, which might have had different results. For example, previous studies have commonly used STAI (Spielberger et al., 1970) to assess anxiety (e.g. Qunsel et al., 2003), BDI (Beck et al., 1961) to measure depression outcome (e.g. Qunsel et al., 2003; Currie et al., 2000) or the Hospital Anxiety and Depression Scale (HADS; Sigmond & Snaith, 1983) (e.g. Savard et al., 2005; Casault et al., 2015; van Straten et al., 2009), whereas the current study used DASS-21 (Lovibond & Lovibond 1995). The DASS-21 measurement was selected for the current study, mainly because it assesses depression and anxiety as well as stress, which is the most common precipitating factor in insomnia (Morin, 1993). Therefore, it was important for the current study to assess whether significant improvements in sleep lead to a reduction in symptoms of stress.

Despite the lack of significant pre-and-post intervention differences in depression and anxiety symptoms, participants following the intervention showed a significant reduction in stress levels. It may be argued that physiological changes caused by stress that can trigger or exacerbate sleep are more modifiable in comparison to more clinically significant mental health problems (e.g. depression and anxiety). Consequently, the current findings suggest that a brief CBT-I SH booklet may be effective in reducing moderate levels of arousal which, in turn, suggests that a brief CBT-I SH booklet may help patients become more relaxed and less over-reactive and may improve sleep patterns. However, only one study has assessed the effectiveness of a CBT-I self-help booklet in relation to perceived stress in daily life, and it similarly found that a CBT-I SH booklet with support is effective in reducing stress (as measured by the Perceived Stress Scale (PSS-10; Cohen, Kamarck, & Memelstein, 1983) in patients with comorbid insomnia (e.g. Jermelov et al., 2012). Also, the same study, when comparing the CBT-I SH booklet without therapist control with waiting list patients, did not show a significant reduction in stress. Accordingly, the current results of the study further contribute to evidence, which indicates that CBT-I without therapist support may significantly reduce stress in a non-clinical sleep disturbance population with chronic health conditions.

As previously discussed, cognitions play a vital role maintaining sleep problems (Morin, 1993). The findings suggest that a CBT-I SH booklet can also be effective in reducing dysfunctional beliefs and attitudes about sleep. This finding is consistent with previous SH studies with clinical (e.g. Casault et al., 2015; Rybarczyk et al., 2005; Jermelov et al., 2012; Rybarczyk et al., 2011) and non-clinical populations (e.g. Van Straten et al., 2009; Mimeault & Morin, 1999) where a CBT-I SH intervention was used. Also, the current findings, in relation to sleep-related dysfunctional beliefs, are in line with previous studies on delivering group CBT-I to clinical populations (e.g. Rybarczyk et al., 2002; Rybarczyk, et al. 2005; Kapella et al., 2011).

Consequently, an important finding that adds further support to the selection of the multicomponent CBT-I intervention of the current study comes from Edinger et al. (2001) who assessed the specific effects of CBT-I on sleep-related dysfunctional beliefs. Specifically, Edinger et al. (2001) found that participants with primary insomnia, who received a multicomponent CBT-I, showed a greater reduction of sleep-related dysfunctional beliefs compared to participants who received progressive muscle relaxation or a placebo and these improvements were maintained over the long-term. Furthermore, these changes were associated with both subjective and objective measurements of insomnia symptoms in the CBT-I group (Edinger et al., 2001). Finally, the authors stated that CBT-I is a beneficial treatment compared to behavioural since it corrects specific sleep-related dysfunctional cognitions. Another study found that a CBT-I group showed higher improvement in dysfunctional beliefs and attitudes about sleep compared to a pharmacological group for insomnia and these reductions were associated with improved sleep maintenance at follow-up (Morin, Blais & Savard, 2002).

Collectively, these findings indicate that any treatment that does not target cognitions might have an effect on dysfunctional beliefs. However, a CBT-I intervention directly targets dysfunctional cognitions, leading to greater reductions in sleep-related dysfunctional beliefs. Accordingly, the above findings (e.g. Edinger et al., 2001; Morin et al., 2002) may be related to the findings of the current study since the intervention directly addressed cognitions. Also, it may be argued that participants have learned to manage better negative sleep-related beliefs. Potentially, the

improvements in sleep outcomes may be related with the reduction of sleep-related dysfunctional beliefs.

With regard to HRQoL, the findings suggest that the CBT-I booklet used for the current study does not have an effect on HRQoL (both mental and physical). Whereas, previous studies have shown that a CBT-I SH can improve the general population's mental well-being as measured by SF-36, but not overall quality of life (e.g. van Straten et al., 2009). Also, other self-administrated CBT-I interventions on patients with cancer showed no improvements to global quality of life but significant improvement in cognitive functioning (e.g. Casault et al., 2015). On the other hand, other CBT-I group studies in older adults with various chronic health conditions found no significant difference to daytime functioning (e.g. Rybarczyk, et al., 2002; Rybarczyk, et al. 2005), whereas, a group-CBT based study of patients with cancer showed significant improvement to global quality of life (e.g. Savard et al., 2005).

In sum, as with anxiety and depression, the findings with respect to HRQoL are mixed. The lack of significant improvement to HRQoL for the current population may be attributable in various ways. Firstly, HRQoL (both mental and physical components) might be related to the symptoms of their chronic health condition rather than to sleep. The sample of the current study was diverse with regard to the type of chronic health condition or it had multi-morbidity conditions, which might have affected the HRQoL. It is also possible that six-weeks was not long enough period for patients who have had sleep disturbance from two months to 40 years to show a measurable improvement in HRQoL. Therefore, for the current sample it might be possible that patients who experience sleep problems over long-term period may require a different or more intensive approach, such as the delivery of CBT for a longer-period, in order to show improvements to HRQoL. For example, as implied within the framework of Espie's (2009) stepped care model for insomnia, individuals may progress to more intensive treatment over time.

Overall, consistent with previous studies, the current findings suggest that CBT-I SH booklet without support can be effective in improving sleep in populations with non-clinical sleep disturbance or subclinical insomnia and chronic health conditions. In addition, the current findings show a reduction in stress and sleep-related

dysfunctional beliefs. On the other hand, no significant improvements were found for depression, anxiety and health-related quality of life.

The current study has provided significant implications for both research and clinical practice in sleep research. These are considered below.

### **5.1. Study Implications both in research and clinical practice**

The current study has several research and clinical implications. The most significant implication of the current study, both in research and clinical practice, is the real-world perspective and approach of the current study towards sleep research, specifically in studying participants with non-clinical sleep disturbance and chronic health conditions, rather than comorbid insomnia among patients with chronic health conditions. Certainly, the unique approach of the current study, in relying on individuals with self-reported sleep disturbances and administering a holistic intervention, proved beneficial to this group of participants. These findings suggest that a brief, cost-effective and timely intervention may prevent the development of more severe sleep disturbance problems for patients with chronic health conditions. Furthermore, the current study showed that sleep and stress improved, demonstrating that sleep disturbance may not be related to clinical indicators such as depression and anxiety. Overall, within the field of health psychology, the current study contributes by its novel approach towards sleep research.

Additionally, in terms of research, the current study highlighted and addressed the gap in the existing literature by considering patients with chronic health conditions and non-clinical sleep disturbance since this group of individuals has been largely ignored in the existing literature. In particular, the current study showed that individuals with non-clinical sleep disturbance undeniably experience poor sleep quality, moderate severity of insomnia and the levels of their psychological symptoms differ from normal profiles, and it established that this group of participants warrants further evaluation and effective treatment. Hence, the current study added to and extended the current literature that CBT for sleep problems in the form of a self-help booklet without professional support is an effective treatment in

alleviating sleep problems, reducing stress and sleep-related dysfunctional beliefs for patients with non-clinical sleep disturbance or sub-clinical levels of insomnia.

In terms of clinical practice, CBT for sleep in the form of a SH booklet can be an effective treatment and can be considered as a good first step approach (Espie, 2009) for treating patients with various chronic health conditions and non-clinical sleep disturbance, including also those with sub-clinical levels of sleeping difficulties. Specifically, the provision of CBT-I in the form of a SH booklet may be particularly useful in clinical settings since it may be regarded as a convenient, cost-effective and flexible approach as it can certainly reach a large number of patients with various functional difficulties. Also, it may be useful in clinical settings where CBT may not be a viable treatment option due to lack of trained therapists, time etc.

Accordingly, the current study further suggests that a brief CBT-I SH booklet may be effective and may be easily implemented in clinical settings (e.g. outpatient clinics) with patients with various chronic health conditions and sleep-related problems.

In addition, the evaluation at the end of the intervention showed participants' satisfaction and approval of the treatment. For example, 50% of participants rated the intervention as good and 71.7% stated that they definitely or might recommend the published CBT-SH booklet to other patients with sleep-related problems.

Overall, the current study contributes significantly to both clinical and research practice by viewing sleep from a real-world perspective and by further showing the effectiveness and applicability of a brief CBT intervention for sleep problems in the form of a self-help booklet among patients with non-clinical sleep disturbance or sub-clinical levels of insomnia.



## **5.2. Strengths and limitations**

### **5.2.1. Strengths**

An important strength of the current study is that it was carried out and implemented as close as possible to a real-world context of sleep rather than being implemented as a controlled sleep study (e.g. identifying or screening participants with insomnia prior to the delivery of the intervention). Specifically, we relied on individuals' self-report of sleep complaints/problems and without excluding any participants that did not meet the clinical cut-off score of the PSQI (e.g. 3 participants had a score of  $<5$ = good sleepers).

The current real-world approach further adds and shows that an individual's own perception of having sleep-related problems needs to be taken into account since the results showed that the majority had poor sleep quality, clinical insomnia and mean moderate levels of psychological symptoms (e.g. anxiety, depression and stress). However, with regard to individuals who do not meet the cut-off score criteria or did not show severe sleep problems, an early treatment on sleep may be particularly relevant and of benefit to those individuals experiencing milder and more severe sleep problems.

Furthermore, the assessment measurements used in the current study are well validated and the measurements were completed and sent by post without any face-to-face contact and with no professional support from the researcher throughout the intervention (e.g. without minimal therapist support). Accordingly, the methodological approach towards sleep within a real-world context and the inclusion criteria of the current study highlight the suitability of the brief CBT-I self-help booklet within clinical practice.

Additionally, the current study was carried out within a clinical context. Specifically, the participants were recruited from two specialised outpatient clinics and health professionals confirmed the patients' diagnosis prior to taking part in the study. The sample was relatively heterogeneous concerning the type of their chronic health condition and type of sleep problem. For example, patients were included in the study with various chronic health conditions (e.g. lupus, osteoarthritis, arthritis, chronic pain and IBS) and/or with multi-morbidity of conditions and different types

of sleep-related problems (e.g. included in the study if they self-reported sleep disturbance). Also, the current sample was heterogeneous with regard to the various degrees of sleep-related problems and psychological symptoms (normal, mild, moderate, anxiety, depression and stress symptoms). Consequently, the current study has a means to guarantee that the findings can be generalisable in clinical outpatients settings in patients with various chronic health conditions, different sleep-related problems and psychological symptoms.

In sum, the current study was based on a real-world context and the inclusion criteria were liberal, which maximizes the generalisability of the current results.

Despite its strengths, the current study admittedly has several limitations. These are further stated below.

### **5.2.2. Limitations**

The first limitation concerns the repeated measures design of the current study, since there was there was no control group. Randomized controlled trial (RCT) is considered as the most robust scientific method for assessing the effectiveness of an intervention within health care (Akobeng, 2005). On the other hand, since repeated measures design uses the same participants in every condition (Shuttleworth, 2009), participants acted as their own control by using their pre-assessment intervention scores in order to deal with the lack of a control group.

Another limitation is that it is unknown whether the effects of the treatment intervention were maintained in the long-term since the current study did not include follow-up assessments (e.g. 6-month, 12-month etc.).

Furthermore, the current study did not reach the target sample size since there was a notable dropout rate (56%) at post-treatment follow-up assessment. Whereas the current sample size was adequate enough to show a significant difference, it was relatively small ( $n=49$ ). The high attrition rate of the current study differs from previous studies in the related area of CBT-I self-administrated interventions since previous studies had much lower dropout rates. A reasonable explanation in relation to this might be that participants in the current study were recruited from a clinical context. Whereas previous studies recruited participants from the community using

various methods such as advertisements, media websites and memberships of mailing lists groups etc. (e.g. Mimeault & Morin, 1999; Jermelov et al., 2012; Rybarczyk et al., 2011). However, the dropout rate is not surprising for clinical based study since patients may have higher severity symptoms of their illness or be less motivated compared to patients recruited from the community. Another reason that might have influenced the dropout rate is that the current study required a high degree of commitment (e.g. eight weeks overall, including pre-and-post assessments and a 6-week intervention) that may be also be related to the methodological disadvantages of the repeated measures design (e.g. participants may become tired, which increases the likelihood of an elevated dropout rate) (Shuttleworth, 2009). Finally, another reasonable explanation might be the lack of support during the intervention, though, as we had a telephone contact reminder regarding the post-assessments, it was possible to outline some reasons for the withdrawal of participants from the current study. For example, the reasons were mainly related to their chronic health condition (e.g. flare-up, hospitalisation, etc.) or due to a change of attitude towards the study, workload demands, family/work stressors or going away on holiday. Additionally, statistical analyses comparing participants who completed the study with those who did not further added that the dropout rate was not related to demographic characteristics or outcome measures between the two groups.

In addition, since it was a real-world study and since the current study aimed to maximize generalisability, the sample was heterogeneous as discussed above with respect to the type of chronic health conditions and sleep-related problems. However, this makes it difficult to generalise the results since the sample was relatively small. Also, participants were not excluded from the study if they were taking sleep medication or were currently undertaking any psychological treatment. But it is worth noting that only three participants reported having sleep medication and only one participant reported using relaxation tapes. Besides, it was considered both unethical and unfeasible to control for other confounding variables (such as medication for their chronic health condition that might have had sleep improvement effects). Thus, it is not clear if the effects of the treatment were due to the CBT-I SH booklet effect or to medication in relation to their chronic health condition, or related

to improvements in the symptoms of their chronic health condition, which subsequently improved sleep.

Furthermore, the majority of the sample had similar demographic characteristics that might limit the generalisability of the results. For example, the majority of the participants had a good to high educational level so one might consider that they had good literacy skills. Consequently, it is unknown whether a CBT-I SH booklet is effective for patients with a lower educational level. A statistical analysis showed that there was a difference between highly educated participants and poorly educated participants. Also, the sample of the current study had a female preponderance, probably because insomnia is more common among women than men (Morgan, Kucharczyk & Gregory, 2011). On the other hand, this reduces the generalisability of the study findings to men with chronic health conditions and sleep problems. Finally, since the majority of our sample were Scottish, there is no means to ensure that the current results may be representative of the clinical population in other countries since individuals from other countries may have different perceptions of their illness and/or treatment, and different demographic characteristics, any/all of which might affect the results.

Overall, the current results are difficult to be generalised across a wider-variety of population. Collectively, these factors constrain the generalisability of findings and highlight the need for further research involving other clinical populations.

Finally, an important aspect concerning the self-help approach is the adherence of the individual with the treatment. The intervention evaluation questionnaire and the diary frequency (e.g. the use of the self-help booklet) obtained from the participants after the completion of the treatment was beneficial in terms of evaluating participants' approval of and satisfaction with the current treatment and confirming the use of the CBT SH booklet over a period of six weeks. However, since it was a multicomponent CBT SH booklet, it is not clear whether participants read all the treatment CBT SH booklet and/or which components were the most helpful for participants and which techniques participants might have followed and practiced. A more practical adherence logbook (e.g. "please state whether you followed sleep hygiene instructions," etc.), and more in-depth analyses of participants' perceptions

would be beneficial since it would enable an evaluation of which component was the most beneficial. For example, it may be argued that only one component in particular was particularly effective in patients with mild sleep difficulties that may underly the current findings.

Overall, taking into account both its strengths and limitations, the current study provided insight for future studies in the related field.

### **5.3. Future recommendations**

Further studies into the area are warranted to establish the relationship between psychological factors and non-clinical sleep disturbance in patients with chronic health conditions and to further examine the effectiveness of self-administrated CBT-I for patients with non-clinical sleep disturbance with chronic health conditions. In particular, future studies with a diverse methodological design, e.g. study design, outcome measures (e.g. stress and maladaptive sleep habits), different groups of patients with chronic health conditions, long-term follow up and larger sample sizes, with diverse sleep problems. For example, with regard to study outcomes, it is noted in the literature that stress is the most common precipitating factor for sleep problems and other factors maintaining sleep include maladaptive sleep-habits and sleep-related dysfunctional beliefs (Morin, 1993). The current study assessed stress but there is limited evidence in the existing literature for further addressing this factor as well as maladaptive sleep habits. Therefore, future studies with diverse methodological methods, larger sample size and randomized experimental design should aim to examine whether CBT has an effect on such outcomes in order to provide robust evidence of the effectiveness of CBT for sleep-related problems in patients with chronic health conditions.

It would also be beneficial to further examine whether therapist support is essential for patients with various chronic health conditions and non-clinical sleep disturbance, including individuals with sub-clinical sleep difficulties, since the data from previous studies on patients with primary or comorbid insomnia is still inconclusive. For example, future studies need to examine the effectiveness of CBT-I

self-help with therapist support vs. without it, as well as the adherence levels of participants to the intervention with and without therapist support.

Furthermore, it may be possible that non-compulsory contact support might have an impact on participants' adherence and/or increase participants' motivation towards the intervention. Moreover, it might be a helpful alternative approach for individuals who need support throughout the intervention.

Future studies may further evaluate whether all the components of CBT-I are essential and which are the most beneficial techniques for patients with chronic health conditions, either with non-clinical sleep disturbance or sub-clinical sleep difficulties. For example, such studies may tailor the intervention treatment content to patients' characteristics or needs (e.g. for highly anxious participants, progressive muscle relaxation might be an appropriate technique). Future studies can further examine participants' characteristics to show who benefits and who does not benefit from a multicomponent CBT-I. Additionally, future research is needed to examine which component is the most effective by comparing different behavioural interventions for sleep-related problems in patients with chronic health conditions.

Also, it is reasonable to argue that CBT-I SH may be a cost-effective approach since it requires fewer resources (e.g. less specialist time or without therapist support). Since insomnia is associated with high costs, it is important to provide an effective and low-cost treatment, despite the severity of the sleep problem, and also to further examine the cost-effectiveness of such interventions within healthcare.

Furthermore, Internet-based treatment is a novel and promising mode of delivering CBT-I (Espie, 2009) since it has become widely accessible to the public with an increasing number of people using it nowadays. Several recent studies have shown the effectiveness of Internet-delivered CBT-I in a non-clinical population (e.g. Espie, Kyle, Williams et al., 2012; Ritterband et al., 2009; Strom, Pettersson & Anderson et 2004) and in patients with psychiatric conditions and sleep problems (e.g. Vincent & Lewysky, 2009). The Internet might be considered a more favourable method of delivering such interventions to individuals that are computer literate and would perhaps find it preferable. Consequently, for future studies interested in administering a CBT-I intervention through Internet-based platforms, it would be

beneficial, prior to the implementation of the study, to assess the needs of the current population (i.e. a pilot study before the implementation of the intervention).

#### **5.4. Summary and Conclusion**

The current study highlights and demonstrates that patients with non-clinical sleep disturbance deserve early, brief and effective treatment for sleep-related problems. Within its limitations and strengths, the current study shows that CBT-I in the form of a self-help booklet, can improve sleep quality, reduce insomnia symptoms as well as related sleep related-dysfunctional beliefs and stress symptoms in this relatively heterogeneous clinical sample with non-clinical or sub-clinical sleep difficulties. However, the present results suggest that CBT-I self-help booklet is not effective in reducing anxiety and depression symptoms and improving health-related quality of life.

In terms of its implementation, CBT-I self-help intervention in the form of a booklet can be considered as a practical treatment intervention as it is easily administrated, relatively inexpensive (e.g. fewer resources), not time-consuming either for health professionals or patients, it can be easily delivered and can also benefit a wide range of the population. Overall, a brief CBT-I self-help booklet is effective for patients with chronic health conditions and non-clinical sleep disturbance in clinical settings.

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## **APPENDICES**

## **APPENDIX 1: Research Ethics Committee (REC) Approval**

## **APPENDIX 2: Research and Development (R&D) Approval**

### **APPENDIX 3: Participant Information Sheet**

## **APPENDIX 4: Consent Form**

## **APPENDIX: 5 Intervention letter**

## **APPENDIX 6: Demographic Characteristics Questionnaire**



## **APPENDIX 7: Pittsburgh Sleep Quality Index (PSQI)**

## **APPENDIX: 8 Insomnia Severity Index (ISI)**

**APPENDIX 9: Dysfunctional Beliefs and Attitudes about Sleep  
(DBAS-16)**

## **APPENDIX 10: Depression Anxiety Stress (DASS-21)**

## **APPENDIX 11: Health-Related Quality of Life (HRQoL)**

## **APPENDIX 12: The CBT Intervention**

## **APPENDIX 13: Diary**

## **APPENDIX 14: Participant Evaluation**



## **APPENDIX 15: Intervention Evaluation Scores**

## **APPENDIX 16: Usage of the CBT Self-help booklet**